EPA Registration Number

72500-EUP-2 V 1

Jacobs, William

From: sue@kaputproducts.com on behalf of Sue Valentine <sue@scimetricsltd.com>
Sent: Friday, March 28, 2014 4:51 PM
To: Baris, Reuben; Jacobs, William; Benbow, Gene; Urbanski, Jennifer
Cc: richard@genesislabs.com
Subject: Wild Pig Conference

I wanted to send a quick email to let you know about the International Wild Pig Conference in Montgomery AL this April 14th.
Here is the link with general information. Click "View Agenda" to get a listing all speakers.

http://www.wildpigconference.com/

Let me know in case any of you are attending.

Thanks, and enjoy your week-end! Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Welcome, It's Tuesday, April 01, 2014

- **2014 conference**

- Home
- Agenda
- Travel
- Register
- Sponsor
- Contact Us

- **Past Conference:**

- 2012 International Wild Pig Symposium
- 2010 International Wild Pig Symposium

2014

International Wild Pig Conference

New this year!
All day technical training on Monday, April 14.
VIEW THE AGENDA

From the conference organizers:

Welcome to the International Wild Pig Conference website! For over the past year (and for the coming year) we have been working diligently to put together a first-class conference to showcase the latest in wild pig research and management. As with our previous wild pig conferences, we anticipate another highly informative forum on wild pig biology, genetics, and behavior, damage assessment, diseases issues, management techniques, and human dimensions of wild pig management for managers, researchers, and policy makers.

New to wild pig management? No problem, we got you covered! New for this year is our Technical Training Session that will be held on Monday, April 14. Featuring wild pig experts from around the country, this full-day session will be your introduction to "Everything Wild Pig" from defining the scope of the problem,to wild pig biology and ecology, to the pros and cons of various in-the-field management techniques. Our goal is to provide you everything you need to know about wild pigs and

their management in 8 hours! Needless to say, this session will be jam-packed with science-based information and will move along at a quick pace.

We hope that you join us!

Mark Smith and Steve Ditchkoff
On behalf of the Wild Pig Conference Committee

About the Conference

Damage caused by wild pigs is one of the greatest concerns to wildlife biologists and managers today. Wild pigs have the potential to cause ecological and economical destruction far surpassing any other invasive exotic vertebrate. The adaptive and prolific nature of these animals along with their capabilities for widespread devastation places their management as one of the top priorities for wildlife scientists. The International Wild Pig Conference is the only forum in the world that provides federal, state, and private stakeholders a venue to discuss biological, financial, and social implications specific to wild pig subsistence in our ecosystems. The conference will assemble experienced managers as well as those new to the wild pig industry in a professional, educational atmosphere. Please visit our website links to find out how you can participate in the 2014 Wild Pig Conference!

• Sponsored By:

- WS Wildlife Services
- ALABAMA WILDLIFE & FRESHWATER FISHERIES
- ALFA FARMERS
- ALABAMA COOPERATIVE Extension SYSTEM *Your Experts for Life*

- AUBURN UNIVERSITY
  SCHOOL OF FORESTRY AND WILDLIFE SCIENCES
- College of Forest Resources
- JAGER PRO HOG CONTROL SYSTEMS
- MISSISSIPPI STATE UNIVERSITY
- the Westervelt Company

Hosted By:

- School of Forestry and Wildlife Sciences, Auburn University
- Alabama Cooperative Extension System

This page was last updated on 4/1/2014.
Page maintained by Mississippi State University
For information, contact the webmaster

Jacobs, William

From: Jacobs, William
Sent: Thursday, March 27, 2014 2:28 PM
To: 'Sue Valentine'; Baris, Reuben
Cc: Benbow, Gene; Urbanski, Jennifer; richard@genesislabs.com
Subject: RE: PRIA extension 72500-EUP-E
Attachments: KaputFeralHogEUP-Efficacy-032714.docx

Thank you for the prompt response regarding PRIA extension.

Here (attached) are the efficacy comments that we discussed at our meeting yesterday.

These comments are based upon the original application plus the Davis (2008) paper that you provided last year. To the extent that the type of use site and the study procedures change (also discussed yesterday), some of the comments in the attachment might no longer apply.

If you have questions regarding these comments, you may reach me via direct response to this note or via telephone at 703-305-6406.

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Thursday, March 27, 2014 1:14 PM
To: Baris, Reuben
Cc: Jacobs, William; Benbow, Gene; Urbanski, Jennifer; richard@genesislabs.com
Subject: PRIA extension 72500-EUP-E

Reuben:
First of all, Richard and I would to thank you and your team for meeting with us yesterday. We feel it was a very constructive meeting, and we will be working with you to resolve the various subjects we discussed.

To begin with, I have attached a letter of agreement to move the PRIA date for our Feral Hog EUP to June 4th. We are working on narrowing the scope and getting more details regarding USDA collaboration, and we will be emailing that to you in the near future.

Thanks again to everyone, and best regards,
Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

It is not clear that prior research has established that 0.005% is the appropriate concentration of Warfarin to use in a bait product of this type. The inference of "100% efficacy" drawn from research reported by Davis (2008) is based on the fates of 4 hogs that were exposed for up to 5 days to a bait that was shown by chemical assay to have been 0.00712% (±0.00027%).

Much more could be learned from the proposed research plan if the changes listed below were incorporated.

1. Increasing the number of test plots

2. Adding one or more untreated plots which would be monitored but not treated with toxic bait (placebo bait?)

3. Assessing a higher Warfarin concentration (e.g., 0.01%) as well as 0.005% in the same bait matrix

4. Outlining the procedures that would be followed for the passive tracking index, including how it would be adapted for use in fenced pasture areas

5. Incorporating into the research design a second census method for assessing the effects of treatment

6. Using radio telemetry to document the fates of some hogs exposed in the test situation and to aid in rapidly locating "fresh" victims for necropsy and tissue collection for carcass residue determinations

7. Checking bait dispensers daily (early morning, if possible) to quantify residual amounts of bait spillage around dispensers.

As the proposed research would be conducted in what amount to fenced-pasture areas, the proposed experimental use permit (EUP) label must be revised to include fenced pastures as a permitted use site. Use in unfenced rangeland is prohibited by the proposed EUP label. Consequently, "rangeland" should not be permitted as a use site. Other changes needed for the EUP label are enumerated below. Additional label modifications are likely to be needed if this use pattern is proposed in an application for registration under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

1. Replace the third bulleted item in the "**USE RESTRICTIONS:**" subsection of "**DIRECTIONS FOR USE**" section with the text shown below.

   Apply bait only in fenced areas. Do not use this product in unfenced, open rangelands.

2. Replace the third sentence of the "**BAIT APPLICATION:**" subsection of the "**DIRECTIONS FOR USE**" with the text shown below.

   Continue treatment for 10-21 days. Monitor feeders every 1-5 days. Refill feeders if bait is significantly depleted or degraded and there still is evidence of hog activity at the feeder.

3. In the fifth and sixth sentences of the "**BAIT APPLICATION:**" subsection, change "may have" to "has".

4. Change the subheading "**SURVEILLANCE AND FOLLOW UP:**" to "**SURVEILLANCE AND FOLLOW-UP:**" (i.e., insert a hyphen). In the second sentence of this paragraph, change "2-5 day" to "2- to 5-day". Replace the fourth sentence of this paragraph with the text shown below. Note that a hole dug 18 inches deep would not put the entire carcass of some feral hogs underground.

Bury carcasses on site in holes dug deeply enough that the entire carcass is at least 18 inches below ground level. Cover carcasses with earth up to the level of the surrounding ground.

5. The commas in the last sentence of the "**SURVEILLANCE AND FOLLOW-UP:**" paragraph are not needed and should be deleted.

Jacobs, William

From: sue@kaputproducts.com on behalf of Sue Valentine <sue@scimetricsltd.com>
Sent: Thursday, March 27, 2014 1:14 PM
To: Baris, Reuben
Cc: Jacobs, William; Benbow, Gene; Urbanski, Jennifer; richard@genesislabs.com
Subject: PRIA extension 72500-EUP-E
Attachments: 72500-EUP-E PRIA Extension Letter 03.27.14.pdf

Reuben:
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To begin with, I have attached a letter of agreement to move the PRIA date for our Feral Hog EUP to June 4th. We are working on narrowing the scope and getting more details regarding USDA collaboration, and we will be emailing that to you in the near future.

Thanks again to everyone, and best regards,
Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Scimetrics
Ltd. Corp.

5949936

March 27, 2014

Mr. Reuben Baris, PM#7
Document Processing Desk
Office of Pesticide Programs – 7504P
U.S. Environmental Protection Agency
One Potomac Yard (South Building), Rm S-4900
2777 South Crystal Drive
Arlington, VA 22202

Dear Mr. Baris:

Subject: PRIA Date Extension - Kaput Feral Hog Experimental Use Permit Application
EPA File Symbol **72500-EUP-E**

As per our discussion with Mr. Bill Jacobs and yourself on March 26, 2014 at the Agency, Scimetrics Ltd. Corp. agrees to a PRIA extension for above listed Experimental Use Permit Application. The new PRIA date is now **June 4, 2014**.

Please contact us if you have any questions or if you need any other information at this time.
Contact Information: Sue Valentine, Ph. 970-482-1330, email: sue@scimetricsltd.com

Sincerely,

Sue Valentine

Sue Valentine
Regulatory Manager

Scimetrics
Ltd. Corp.
PO Box 1045 • Wellington, Colorado 80549-1045
970-482-1330 Phone • 970-482-1885 Fax
www.kaputproducts.com

Jacobs, William

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Sent: Thursday, March 27, 2014 1:14 PM
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Thanks again to everyone, and best regards,
Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Scimetrics
Ltd. Corp.

AGENDA FOR EPA MEETING

Attendees on behalf of Scimetrics Ltd. Corp: Richard Poché, Sue Valentine

Date and Time: Wednesday, March 26, 2014
9 am (approx. 45 min)

Location: 2777 South Crystal Drive, Arlington VA

Discussion Points:

Item 1
Addition of vineyards to Scimetrics' Diphacinone baits 72500-9, 72500-11, 72500-12
Examples of labels including vineyards, orchards, groves and other sites are CA SLN 890020 (0.005% DPN) and 890022 (0.01% DPN), PCQ Pelleted Rodent Bait CA SLN 780146 50003-AA (0.01% DPN), Tomcat Ground Squirrel Bait 3 lb. CA SLN 780146 50003-ZA (0.01% DPN)

Item 2
Feral Hog EUP Update

Item 3
72500-24 Kaput Ground Squirrel Bait
CA DPR would like to change wording under "Use Restrictions", and also add "Endangered Species Consideration" to the label before registering it in California

Item 4
Amendment (submitted on 05.21.2008) to add Prairie Dogs to EPA Registration 72500-11:
Scimetrics would like to pursue the addition of a Prairie Dog bait featuring lower concentration of Diphacinone (0.0025%) plus Imidacloprid (0.025%), preferably as a stand-alone label.

Item 5
Procedure to re-activate EPA Registration 72500-16 Kaput-D Vole Bait

Scimetrics
Ltd. Corp.
PO Box 1045 • Wellington, Colorado 80549-1045
970-482-1330 Phone • 970-482-1885 Fax
www.kaputproducts.com

TEXAS DEPARTMENT OF AGRICULTURE

TODD STAPLES
COMMISSIONER

March 17, 2014

Mr. Reuben Baris
Acting Product Manager 07
Registration Division 7505P
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Baris:

The Texas Department of Agriculture (TDA) would like to express support for the issuance of experimental use permits for toxicant baits developed for controlling the feral hog population. According to Texas A&M AgriLife Extension, feral hogs cause an estimated $500 million in economic damage annually in Texas. In addition, feral hogs cause significant environmental and public health concerns.

There are an estimated 2.6 million feral hogs in Texas. Hunting and trapping the hogs is currently the primary means of controlling the population in the state. On average, hunters reduce the feral hog population by 24 percent each year. However, to keep the feral hog numbers from increasing beyond their current population, hunters and trappers would need to remove an average of 50 to 70 percent of the 2.6 million hogs annually. These figures emphasize the immediate need to find alternative methods for controlling the growing hog population. TDA strongly encourages EPA to facilitate the issuance of experimental use permits in accordance with the Pesticide Registration Improvement Extension Act (PRIA 3), which will allow for further needed data collection on toxicant baits.

TDA appreciates the opportunity to comment on this important issue. If you have further questions, please feel free to contact me by email at David.Kostroun@TexasAgriculture.gov or by phone at (512) 463-0012.

Sincerely yours,

David Kostroun
Chief Administrator
Agriculture and Consumer Protection Division

DK/ds

P.O. Box 12847 Austin, Texas 78711 (512) 463-7476 Fax: (888) 223-8861
www.TexasAgriculture.gov

TEXAS DEPARTMENT OF AGRICULTURE

TODD STAPLES
COMMISSIONER

March 17, 2014

Mr. Reuben Baris
Acting Product Manager 07
Registration Division 7505P
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Baris:

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TDA appreciates the opportunity to comment on this important issue. If you have further questions, please feel free to contact me by email at David.Kostroun@TexasAgriculture.gov or by phone at (512) 463-0012.

Sincerely yours,

David Kostroun
Chief Administrator
Agriculture and Consumer Protection Division

DK/ds

P.O. Box 12847 Austin, Texas 78711 (512) 463-7476 Fax: (888) 223-8861
www.TexasAgriculture.gov

Jacobs, William

From: Dale Scott [Dale.Scott@TexasAgriculture.gov]
Sent: Monday, March 17, 2014 4:04 PM
To: Jacobs, William
Cc: Leslie Smith
Subject: RE: EUP Letter
Attachments: Letter to EPA supporting feral hog baits EUP SIGNED 3.17.2014.pdf

Bill,
Please see the attached letter. I will also be sending the original via FedEx. Let me know if there is anything else I can do. Thanks.

Dale R. Scott
Coordinator for Pesticide Product Evaluation and Registration
Texas Department of Agriculture
P.O. Box 12847
Austin, TX 78711
(512) 936-2535 Phone
(888) 216-9860 Fax
dale.scott@TexasAgriculture.gov

From: Jacobs, William [mailto:Jacobs.Bill@epa.gov]
Sent: Thursday, February 27, 2014 9:52 AM
To: Dale Scott
Subject: RE: EUP Letter

You may send it as an attachment to me or to Reuben Baris at baris.reuben@epa.gov

For the business address and/or if you choose to sent it via USPS, use the following address:

Mr. Reuben Baris
Acting Product Manager 07
Registration Division 7505P
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Thank you in advance for the letter.

From: Dale Scott [mailto:Dale.Scott@TexasAgriculture.gov]
Sent: Thursday, February 27, 2014 10:37 AM
To: Jacobs, William
Subject: EUP Letter

Bill,

To whom do I address the letter. Thanks.

Dale R. Scott
Coordinator for Pesticide Product Evaluation and Registration
Texas Department of Agriculture
P.O. Box 12847
Austin, TX 78711
(512) 936-2535 Phone
(888) 216-9860 Fax
dale.scott@TexasAgriculture.gov

********** ATTACHMENT NOT DELIVERED **********

This Email message contained an attachment named
image001.jpg
which may be a computer program. This attached computer program could contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you should contact the sender and request that they rename the file name extension and resend the Email with the renamed attachment. After receiving the revised Email, containing the renamed attachment, you can rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

********** ATTACHMENT NOT DELIVERED **********

Jacobs, William

From: Baris, Reuben
Sent: Tuesday, March 25, 2014 8:29 AM
To: Benbow, Gene
Cc: Urbanski, Jennifer; Jacobs, William
Subject: RE: Wednesday 9 am

I included Bill on the invite since he's working on the EUP and knows Scimetrics quite well.

Thanks for your take on their discussion points. Item #4 is two separate products therefore separate registrations. Item #5 would again I think they need to reapply for an active registration.

REUBEN BARIS | ACTING PRODUCT MANAGER 07 | *U.S. EPA OFFICE OF PESTICIDE PROGRAMS, REGISTRATION DIVISION* | *PHONE: (703) 305-7356*

From: Benbow, Gene
Sent: Tuesday, March 25, 2014 7:33 AM
To: Baris, Reuben
Cc: Urbanski, Jennifer
Subject: RE: Wednesday 9 am

Reuben – do we want Bill on this meeting?

Item #1 – What is the procedure for incorporating a 24c use to a section 3? This is a 'new use' right?

Item #3 – sounds easy

Item #4 – I don't understand this one. I'm pretty sure we would not allow them to carry 2 completely different bait formulations under a single registration, which is what it sounds like they're asking. Heck, we didn't used to even accept alternate formulations (CSFs) for even ***very minor*** changes to the formula of rodenticide products.

Item #5 – No idea, but I'm sure it's fairly expensive and tedious.

Gene Benbow
Biologist, EPA
Insecticides-Rodenticides Branch
Registration Division
http://epa.gov/pesticides/
703-347-0235

From: Baris, Reuben
Sent: Monday, March 24, 2014 5:30 PM
To: Sue Valentine
Cc: richard@genesislabs.com; Urbanski, Jennifer; Benbow, Gene
Subject: RE: Wednesday 9 am

Hi Sue,
We still have you on the schedule for 9 am, and I don't think the snow will be an issue. I may have to drop out early since I have a briefing with the Assistant Administrator at 9:30, but Gene and Jenn are available. I have another meeting from 8-9, so please give Jenn or Gene a call when you have been through security and they will come down to escort you upstairs.

Gene: 703-347-0235
Jenn: 703-347-0156

See you Wednesday.
reuben

REUBEN BARIS | ACTING PRODUCT MANAGER 07 | *U.S. EPA OFFICE OF PESTICIDE PROGRAMS, REGISTRATION DIVISION* | *PHONE: (703) 305-7356*

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Monday, March 24, 2014 4:15 PM
To: Baris, Reuben
Cc: richard@genesislabs.com
Subject: Wednesday 9 am

Hi Reuben:
Just to confirm our meeting this Wednesday at 9 am. We will give you a call once we are in the lobby of the building. Looks like the snow will have moved out come Wednesday. That's a good thing! Talk to you soon, Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Jacobs, William

From: Jacobs, William
Sent: Thursday, March 20, 2014 3:45 PM
To: Laws, Meredith
Subject: RE: feral hog EUP briefing for Lois and Don Brady

OK. I'll whip something up.

From: Laws, Meredith
Sent: Thursday, March 20, 2014 3:43 PM
To: Jacobs, William
Subject: RE: feral hog EUP briefing for Lois and Don Brady

Usually the briefing papers are structured as a ppt. We print them out and provide copies. We don't project them on a screen.

From: Jacobs, William
Sent: Thursday, March 20, 2014 3:03 PM
To: Laws, Meredith
Subject: RE: feral hog EUP briefing for Lois and Don Brady

OK with the April 2 target. I will be taking the EUP jacked home with me this weekend, then. I didn't note that on the Telework outline that I just sent to you.

Would you like me to do up a Power Point in addition to a briefing document or just one or the other?

From: Laws, Meredith
Sent: Thursday, March 20, 2014 2:57 PM
To: Jacobs, William
Cc: Baris, Reuben; Urbanski, Jennifer
Subject: feral hog EUP briefing for Lois and Don Brady

Bill – here's the briefing structure that Lois laid out for the meeting with her and Don, and then up to the Office Director (whoever that is):

Intro – scope of the EUP program, PRIA date
Problems with Feral Hogs, what damage they do
HED conclusions
EFED conclusions, issues
NOR comments received
OGC (David Berol) thoughts
Decision Options/Recommendations

+ add the Question of How to Handle Feral Hog Baits in general – especially now that we have a section 3 in-house, and have had a meeting on another proposed product (the M. Brooks thing)

I'm on travel next week and in an all-day meeting on 3/31. Can you target ~ April 2 for a draft? Thanks.

Jacobs, William

From: Laws, Meredith
Sent: Thursday, March 20, 2014 2:21 PM
To: Corbin, Mark; Davis, Donna
Cc: Urbanski, Jennifer; Baris, Reuben; Jacobs, William
Subject: Heads Up - new use

Mark, Donna:

We just got a section 3 application for the warfarin bait for feral hogs. This was completely unexpected. We haven't even decided whether to issue the EUP. We were briefing that up the chain.

So this is a heads up – you will get it beaned to you next week. Please do a 90-day screen. It's very possible that they don't have a complete package to support this, especially on the EFED and efficacy pieces.

Meredith

Jacobs, William

From: Corbin, Mark
Sent: Tuesday, February 25, 2014 12:05 PM
To: Baris, Reuben; Riley, Elizabeth; Jacobs, William
Cc: Wait, Monica
Subject: RE: Feral Hog EUP, EPA Symbol 72500-EUP-E

Given that we are likely to have some subset of these species present in the three counties I think it would be wise for us to have a short discussion about how to proceed with this. As we have seen with other chemicals dealing with ESA this is not a quick nor an easy task

Mark Corbin
Branch Chief, Environmental Risk Branch 6
Environmental Fate and Effects Division
Office of Pesticide Programs, USEPA
phone - 703-605-0033
fax - 703-305-6309
email - corbin.mark@epa.gov

From: Baris, Reuben
Sent: Tuesday, February 25, 2014 12:03 PM
To: Riley, Elizabeth; Jacobs, William
Cc: Wait, Monica; Corbin, Mark
Subject: RE: Feral Hog EUP, EPA Symbol 72500-EUP-E

We were able to renegotiate the PRIA date to April 4, while more time, not much more....

From: Riley, Elizabeth
Sent: Tuesday, February 25, 2014 11:51 AM
To: Baris, Reuben; Jacobs, William
Cc: Wait, Monica; Corbin, Mark
Subject: RE: Feral Hog EUP, EPA Symbol 72500-EUP-E

Thanks, Rueben!

Bill- I ran a quick LOCATES run for the three counties and it returned 16 listed species (focusing on birds for indirect effects and mammals for both direct and indirect effects). A few of those species we may be able to remove from concern based on various biological attributes but this will require a fairly substantial amount of work. I'm not sure at this point what the timing would be for these additional analyses. Mark- do you have any thoughts?

e

From: Baris, Reuben
Sent: Tuesday, February 25, 2014 8:37 AM
To: Jacobs, William
Cc: Wait, Monica; Corbin, Mark; Riley, Elizabeth
Subject: RE: Feral Hog EUP, EPA Symbol 72500-EUP-E

HI Bill,

When requesting timeline/workload input from Elizabeth be sure to cc Monica Wait (RAPL) and Mark Corbin (BC). Not that Elizabeth won't be able to answer, but Monica and Mark will at least be looped into any additional work Elizabeth will be doing to complete the EUP assessment.
Thanks.
reuben

From: Jacobs, William
Sent: Tuesday, February 25, 2014 7:55 AM
To: Baris, Reuben
Subject: FW: Feral Hog EUP, EPA Symbol 72500-EUP-E

See below.

From: Jacobs, William
Sent: Tuesday, February 25, 2014 7:53 AM
To: Riley, Elizabeth
Subject: FW: Feral Hog EUP, EPA Symbol 72500-EUP-E

See information under Site Selection. The are "looking at an area" at the confluence of 3 counties near the Texas panhandle. It's not quite the one-county scenario that might have been easier to assess, but at least we have something that we can focus upon.

Please indicate how long it should take for EFED's review to be completed, incorporating this new information and a discussion of ESA considerations.

Thank you.

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Monday, February 24, 2014 5:32 PM
To: Baris, Reuben; Jacobs, William
Cc: richard@genesislabs.com
Subject: Feral Hog EUP, EPA Symbol 72500-EUP-E

Reuben, Bill:

Listed below is additional information regarding your questions pertaining to Feral Hog EUP:

Tracking
The monitoring for feral hog numbers will be conducted using two methods.
1. Tracking plots, as described by Engeman et al 2013 (Monitoring wild pig populations: a review of methods). A minimum of 50 tracking plots will be established on treatment and control areas.
2. Trail cameras will be use to monitor activity, as described by Rovero and Marshall 2009 (Camera trapping photographic rate as an index of density in forest ungulates). These will be set up to overlap with the tracking plots.

Data utilizing both methods will be collected during pre- and post-treatment periods.

Site Selection
We are looking at an area in Texas that extends into three counties: Hall, Briscoe and Motley Counties. The area is outlined by following three towns: 1. Turkey (Hall Cty), 2. Quitaque (Briscoe Cty) and 3. Flomot (Motley Cty).

Support Letters
We are still working on getting support letters from different entities, i.e. TX Dept. of AG, Texas A&M University and NC State University.

With best regards,
Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Jacobs, William

From: Riley, Elizabeth
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To: Jacobs, William
Cc: Wait, Monica; Corbin, Mark; Riley, Elizabeth
Subject: RE: Feral Hog EUP, EPA Symbol 72500-EUP-E

HI Bill,
When requesting timeline/workload input from Elizabeth be sure to cc Monica Wait (RAPL) and Mark Corbin (BC). Not that Elizabeth won't be able to answer, but Monica and Mark will at least be looped into any additional work Elizabeth will be doing to complete the EUP assessment.
Thanks.
reuben

From: Jacobs, William
Sent: Tuesday, February 25, 2014 7:55 AM
To: Baris, Reuben
Subject: FW: Feral Hog EUP, EPA Symbol 72500-EUP-E

See below.

From: Jacobs, William
Sent: Tuesday, February 25, 2014 7:53 AM
To: Riley, Elizabeth
Subject: FW: Feral Hog EUP, EPA Symbol 72500-EUP-E

See information under Site Selection. The are "looking at an area" at the confluence of 3 counties near the Texas panhandle. It's not quite the one-county scenario that might have been easier to assess, but at least we have something that we can focus upon.

Please indicate how long it should take for EFED's review to be completed, incorporating this new information and a discussion of ESA considerations.

Thank you.

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Monday, February 24, 2014 5:32 PM
To: Baris, Reuben; Jacobs, William
Cc: richard@genesislabs.com
Subject: Feral Hog EUP, EPA Symbol 72500-EUP-E

Reuben, Bill:

Listed below is additional information regarding your questions pertaining to Feral Hog EUP:

Tracking
The monitoring for feral hog numbers will be conducted using two methods.
1. Tracking plots, as described by Engeman et al 2013 (Monitoring wild pig populations: a review of methods). A minimum of 50 tracking plots will be established on treatment and control areas.
2. Trail cameras will be use to monitor activity, as described by Rovero and Marshall 2009 (Camera trapping photographic rate as an index of density in forest ungulates). These will be set up to overlap with the tracking plots.

Data utilizing both methods will be collected during pre- and post-treatment periods.

Site Selection
We are looking at an area in Texas that extends into three counties: Hall, Briscoe and Motley Counties. The area is outlined by following three towns: 1. Turkey (Hall Cty), 2. Quitaque (Briscoe Cty) and 3. Flomot (Motley Cty).

Support Letters
We are still working on getting support letters from different entities, i.e. TX Dept. of AG, Texas A&M University and NC State University.

With best regards,
Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Jacobs, William

From: sue@kaputproducts.com on behalf of Sue Valentine [sue@scimetricsltd.com]
Sent: Monday, February 24, 2014 5:32 PM
To: Baris, Reuben; Jacobs, William
Cc: richard@genesislabs.com
Subject: Feral Hog EUP, EPA Symbol 72500-EUP-E

Reuben, Bill:

Listed below is additional information regarding your questions pertaining to Feral Hog EUP:

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With best regards,
Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 479666	Registration #: 72500-EUP-E	Petition #:

☐ *See page 2 for additional registration entries*

Chemical Name: Warfarin

Fee Category: R251 — **PRIA Decision Time Frame:** 8 months

Submitted by: Bill Jacobs — **Branch:** OCSPP/OPP/RD — **Date:** 02/20/2014

Company: Scimetrics limited, Corp.

Original PRIA Due Date: 03/03/2014 — **Proposed New PRIA Due Date:** 04/04/2014

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☐ Yes ☑ No ☐ n/a — **If not, date "Fix" expected:** 03/18/2014

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☑ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☑ Labeling	☑ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☑ Ecological			
Interim Consideration	☑ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☑ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☐ Other – Comment Field

Summary of Deficiency Type(s): ☐ **Not Submitted (N)** ☐ **Deficiencies (D)**

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☑ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☑

Additional details on proposed experimental program and revisions to proposed label (including EFED-related items) will be needed.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

Company was most recently contacted on 02/20/14 and is amenable to rapidly providing additional details on program and subsequently providing a revised EUP label. The proposed one-month extension reflects the time period requested by the applicant during discussion with OPP?RD/IRB personnel.

"75 Day" Letter sent? ☐ **Yes, Date sent** ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: ESA matters, experimental program and labeling issues.

Registrant notified that this is the last negotiation? ☐ **Yes** ☑ **Not Applicable**

Approve: ☑ — **Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Marty Monell/OU=DC/O=USEPA/C=US* — **Date:** *02/25/2014*

Decision #: 479666	**Registration #:** 72500-EUP-E	**Petition #:**

Issue(s) (describe in detail):

No 75-day letter was sent because the action is an application for an experimental use permit rather than an application for product registration.

The issue of extending the PRIA date was raised by the Agency rather than requested by the applicant. Consequently, EPA researched the right for future renogotiation, although none seems likely.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf
Form Number: PRIA
Document Identifier: PRIA-14051135208-BJ

SUBMITTED on 02/20/2014 at 02:38:03 PM by CN=Bill Jacobs/OU=DC/O=USEPA/C=US

APPROVED on 02/21/2014 at 09:31:05 AM by CN=Julie Chao/OU=DC/O=USEPA/C=US

APPROVED on 02/24/2014 at 05:49:53 PM by CN=Lois Rossi/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 02/25/2014 at 06:51:23 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

Jacobs, William

From: Laws, Meredith
Sent: Wednesday, February 19, 2014 8:42 AM
To: Jacobs, William
Subject: Re: hog EUP

I don't know the person at TDA, look at the AAPCO website, under the heading "Control Officials."

From: Jacobs, William
Sent: Wednesday, February 19, 2014 7:33:33 AM
To: Laws, Meredith; Berol, David
Cc: Baris, Reuben; Perlis, Robert; Dyner, Mark; Garrison, Scott; Riley, Elizabeth
Subject: RE: hog EUP

Based on conversations with the applicant, it seems likely that TDA knows of the application; but I don't see a letter of support from them in the application package. The 3 supporting comments that we received were from anonymous sources. Who would be the best person at TDA to contact about this?

From: Laws, Meredith
Sent: Wednesday, February 19, 2014 6:59 AM
To: Jacobs, William; Berol, David
Cc: Baris, Reuben; Perlis, Robert; Dyner, Mark; Garrison, Scott; Riley, Elizabeth
Subject: Re: hog EUP

Bill - does the Texas Dept of Ag know about this EUP? If so, did they write a letter of support? Thanks, meredith

---

From: Jacobs, William
Sent: Tuesday, February 18, 2014 3:36:59 PM
To: Berol, David; Laws, Meredith
Cc: Baris, Reuben; Perlis, Robert; Dyner, Mark; Garrison, Scott; Riley, Elizabeth
Subject: RE: hog EUP

Attorney-Client Privileged; Deliberative

[redacted]

Privileged attorney-client communication

[redacted]

From: Berol, David
Sent: Tuesday, February 18, 2014 12:49 PM
To: Jacobs, William; Laws, Meredith
Cc: Baris, Reuben; Perlis, Robert; Dyner, Mark; Garrison, Scott
Subject: RE: hog EUP

Attorney-Client Privileged; Deliberative

[redacted]

Privileged attorney-client communication

[redacted]

David Berol
U.S. EPA Office of General Counsel
202-564-6873
berol.david@epa.gov

From: Jacobs, William
Sent: Tuesday, February 18, 2014 9:02 AM
To: Berol, David
Cc: Laws, Meredith; Baris, Reuben
Subject: FW: hog EUP

Attorney-Client Privilege

[redacted]

From: Laws, Meredith
Sent: Friday, February 14, 2014 5:32 PM
To: Jacobs, William
Subject: hog EUP

Bill – Lois is going to talk to Steve about this. She thought we should tell OGC about it. Please let David Berol know.

Privileged attorney-client communication

Pesticide Control Officials – TEXAS

State Website: http://texasagriculture.gov/

For Reporting Pesticide Incidents: Call 1-800-835-5832

Randy Rivera, Administrator for Agriculture Protection and Certification	
TX Dept. of Agriculture Pesticide Programs Division P.O. Box 12847 Austin, TX 78711	Duties: 1,2 Phone: (512) 463-7717 Fax: (888) 216-9865 Email: randy.rivera@texasagriculture.gov

Stephen Pahl, Administrator for Consumer Protection (Urban/Structural)	
TX Dept. of Agriculture Pesticide Programs Division P.O. Box 12847 Austin, TX 78711	Duties: 1,3,5 Phone: (512) 463-6514 Fax: (888) 205-7224 Email: stephen.pahl@texasagriculture.gov

Janet Fults, Director for Environmental and Biosecurity Programs	
TX Dept. of Agriculture Pesticide Programs Division P.O. Box 12847 Austin, TX 78711	Duties: 4,7,9,10 Phone: (512) 463-8327 Fax: (888) 216-9865 Email: janet.fults@texasagriculture.gov

Perry Cervantes, Coordinator for Pesticide Certification and Compliance (Ag)	
TX Dept. of Agriculture Pesticide Programs Division P.O. Box 12847 Austin, TX 78711	Duties: 4,5,10,11 Phone: (512) 463-7692 Fax: (888) 216-9852 Email: perry.cervantes@texasagriculture.gov

David Villarreal, Environmental Quality Specialist	
TX Dept. of Agriculture Pesticide Programs Division P.O. Box 12847 Austin, TX 78711	Duties: 8, 9 Phone: (512) 463-7481 Fax: (888) 216-9865 Email: david.villarreal@texasagriculture.gov

Pesticide Control Officials – TEXAS

Rafael Paonessa, Certification and Worker Protection Specialist	
TX Dept. of Agriculture Pesticide Programs Division P.O. Box 12847 Austin, TX 78711	Duties: 4,7 Phone: (512) 463-1102 Fax: (888) 216-9865 Email: rafael.paonessa@texasagriculture.gov

Dale Scott, Coordinator for Pesticide Product Registration and Evaluation	
Texas Department of Agriculture Pesticide Division P.O. Box 12847 Austin, TX 78711	Duties: 3 Phone: (512) 936-2535 Fax: (888) 216-9860 Email: dale.scott@texasagriculture.gov

Leslie Smith, Director for Consumer Protection (urban/Structural)	
Texas Department of Agriculture Pesticide Division P.O. Box 12847 Austin, TX 78711	Duties: 1,2,3,5,10,11 Phone: (512) 475-1620 Fax: (888) 216-9852 Email: leslie.smith@texasagriculture.gov

Michael Kelly, Coordinator for Structural Pest Control Service	
TX Dept. of Agriculture Pesticide Division P.O. Box 12847 Austin, TX 78711	Duties: 10,11,5 Phone: (512) 463-2586 Fax: (888) 232-2755 Email: michael.kelly@texasagriculture.gov

Patrick Bizzell, Dir. for Pesticide Residue Laboratory	
TX Dept. of Agriculture 1500 Research Parkway Suite B100 College Station, TX 77845	Duties: 6 Phone: (979) 458-4213 Fax: (888) 216-9853 Email: patrick.bizzell@texasagriculture.gov

Privileged attorney-client communication

Jacobs, William

From: Jacobs, William
Sent: Tuesday, February 18, 2014 9:02 AM
To: Berol, David
Cc: Laws, Meredith; Baris, Reuben
Subject: FW: hog EUP

Attorney-Client Privilege

[redacted]

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To: Jacobs, William
Subject: hog EUP

Bill – Lois is going to talk to Steve about this. She thought we should tell OGC about it. Please let David Berol know.

thanks

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

PC Code: 086002
DP Barcode: 413038
Decision #: 479666

MEMORANDUM **February 6, 2014**

Subject: EFED Response to Scimetric's Request for an Experimental Use Permit to use Kaput® Feral Hog Bait (Warfarin) on Feral Hogs (*Sus scrofa*) in Texas

To: William Jacobs, Risk Manager Reviewer
Reuben Baris, Risk Manager
Registration Division (7505P)

From: Elizabeth Riley, M.S, Biologist
Environmental Risk Branch 6
Environmental Fate and Effects Division (7507P)

Through: Mark Corbin, Branch Chief
Environmental Risk Branch 6
Environmental Fate and Effects Division (7507P)

The Environmental Fate and Effects Division (EFED) has reviewed the proposed Experimental Use Permit (EUP) for use of warfarin (PC Code 086002) and its end-use product Kaput® Feral Hog Bait to control feral hogs (*Sus* scrofa) in Texas. The following

1. P. 7: "Place 25-100 pounds of bait into each feeder". Is there a maximum number of feeders that can be placed in a certain area?

2. P. 7: "Collect and properly dispose of all bait that may have spilled outside the feeder". For the purpose of the EUP, an effort should be made to measure the amount of bait that is spilled outside the feeder. This information could be used to quantify the potential for risk to non-targets.

3. P. 9: The Warfarin Toxicity Data table refers to chronic oral LD50 data as reported in Timm, 1994. Is it possible to view the underlying data sets and/or study designs?

4. P.12: "All test animals that consume the test product will be sampled to determine residue levels". How will samples be taken, analyzed and reported? This residue data will provide valuable information to assess potential secondary risks from feral hog uses. Individual measurements are preferred.

5. P. 15: "With multiple doses required, non-target poisoning is much less likely because the non-target animals will need to consume multiple doses in succession to receive a lethal dose". Label language requires the feeder be "refilled as needed, approximately every 2-5 days depending on number of feral hogs visiting the feeder" (p. 7). Based on this label language, spilled bait may be available for non-target animal consumption for up to 5 days, providing ample opportunity for multiple feedings. Quantification of spilled bait around the feeder would help reduce uncertainties associated with the potential for primary exposure and subsequent risks to non-target species.

6. P. 16: "The bait stations will be continuously monitored by motion activated camera to assure that non-target animals are unable to gain access to the bait". If non-target animals are observed gaining access to the bait, how will the HOGHOPPER or exposure scenario be modified to limit this? Again, an effort should be made to quantify spillage.

7. P. 16: "The bait is specifically designed for optimal palatability for feral hogs and as such it is likely that many non-target animals will not find it palatable". Are data available to support the palatability claims? The available efficacy study (Genesis Study Number N08019) mentions that strawberry flavoring is palatable to pigs but not other species but does not provide supporting references.

8. P. 16: "The bait stations will be regularly monitored and if spillage of bait is observed it will be removed to prevent non-target access". How frequently will stations be monitored? According to the label, the applicator is required to return to the site within 4 days after the initial application and at 2-5 day intervals thereafter. Based on this information, spilled bait may be available for non-target consumption for up to 5 days. Quantification of spilled bait around the feeder would help reduce uncertainties associated with this potential exposure.

9. P. 17. Primary risks analysis: Based on analyses conducted for the Scientific Advisory Panel (SAP) on the Notice of Intent to Cancel non-compliant rodenticide products, primary risks are still triggered for small, medium and large mammals from the proposed bait concentration for feral hogs. RQs range from 1.1 to 1.5, which are above the level of concern for listed and non-listed species. Quantification of spillage from bait stations will help reduce uncertainties associated with potential primary risks. Primary risks to birds are not anticipated.

10. P. 18: Half-life data: Available half-life data for the domesticated pig indicate a liver retention time of 30 to 40 days (O'Brien et al 1987). For other species the liver half-life ranges from 4 to 5 days.

11. P. 18: Secondary risks analysis: Based on analyses conducted for the SAP on the Notice of Intent to Cancel non-compliant rodenticide products, secondary risks are still triggered for small and large mammals from the proposed bait concentration for feral hogs. RQs range from 0.16 to 3.91, which are above the level of concern for listed and non-listed species. Residue levels in feral hogs resulting from the EUP will help reduce

uncertainties associated with potential secondary risks from consumption of hog carcasses. Secondary risks to birds are not anticipated.

Jacobs, William

From: Jacobs, William
Sent: Thursday, January 23, 2014 12:52 PM
To: Laws, Meredith
Cc: Baris, Reuben
Subject: KAPUT FERAL HOG BAIT, 72500-EUP-E
Attachments: KAPUT HOG EUP - Summary for Management -2014-0123.docx

Here (attached) is a brief summary document for this action.

Product: KAPUT® FERAL HOG BAIT, 72500-EUP-E

Applicant: Scimetrics, Inc., Wellington, CO

PRIA Date: March 3, 2014 (pre-decisional date is February 14, 2014)

Proposal: Experimental use permit application for using a 0.005% Warfarin bait block formulation in large bait dispensers to control feral hogs (*Sus scrofa*)

Product: 0.005% Warfarin one-ounce bait block, essentially one inch cubed in dimensions.

Review Status

HED: Completed 12/19/2013 (no objections)

EFED: Pending (preliminary comments received via e-mail on 9/3/2013)

RD/IRB: Completed 10/23/2013 (label changes and program modifications desired)

Details

Efficacy trial is to be run in one or a few fenced pastures in or near the panhandle area of Texas.

The proposed upper limit on test area is 10 km^2 (2,471 acres).

The proposed maximum amount of bait is 12,000 lbs, containing 0.63 lbs of Warfarin (at 0.005% Warfarin, one-fifth the strength of typical Warfarin baits used to control commensal rodents).

Applicant is persuaded by prior research with confined subjects the 0.005% Warfarin concentration is adequate for controlling feral hogs. As that level, Warfarin residues in carcasses of poisoned animals could be relatively low, although carcass of a poisoned hog would provide large amount of tainted meat at a point source.

Summary and Discussion of Issues:

Proposal is for limited experimental use of an anticoagulant compound to kill a large feral animal that is associated with economic and public- and animal-health issues but also is hunted by humans for sport and food. Any action associated with the poisoning of feral hogs may lead to challenges on grounds of appropriateness, necessity, ethics, and humaneness. Public comments on the proposed program were few in number and generally in support of the action. The only negative response came from someone concerned about possible use of the bait in Oregon, many miles away from the proposed Texas study area.

Proposed research is limited in scope and, consequently, is unlikely to provide data sufficient for registration, regardless of the outcome. The bait used in preliminary research was nominally 0.005% Warfarin but assayed at 0.0071%, so 0.005% might not be a sufficient level. In fun, the proposed limited field trial could provide an answer as to the sufficiency of the 0.005% concentration. The proposed

formulation includes a blue dye that marks fatty tissue, thereby providing evidence of exposure (although dose/response for this indicator is not fully established). As the dye has been found in past research by EPA to drastically reduce acceptance of rat and mouse challenge diet by Norway rats and house mice, it might have similar effects on bait uptake by hogs.

RD's review and EFED's preliminary comments list desired additions to the proposed research. These matters would not necessarily have to be addressed under the currently proposed research program but likely would have to be prior to registration of the proposed use.

Jacobs, William

From: Hawkins, Monica
Sent: Thursday, January 16, 2014 7:15 AM
To: Jacobs, William
Cc: Hawkins, Monica
Subject: FW: Final Work Product - Warfarin (086002); DP413046

It's attached below.

MONICA HAWKINS, PH.D., M.P.H.
U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
RISK ASSESSMENT BRANCH VI
(703)305-6459
HAWKINS.MONICA@EPA.GOV

From: Harris, Sharlita
Sent: Friday, December 20, 2013 11:41 AM
To: Jacobs, William
Cc: May, Brenda; Britten, Anthony; Sahafeyan, Mohsen; Hawkins, Monica; Yang, Yung; Housenger, Jack; Rowland, Jess; Vogel, Dana
Subject: Final Work Product - Warfarin (086002); DP413046

The HED work that you requested is now complete. Here is the link to the **signed PDF** of the final document ===> D413046

If you prefer the hard copy of this final document it will be available for pick up for the next 2 weeks in the **HED Final Work Pickup site** (file cabinet) on the 10th floor across from **S-10720.**

Please note that Final HED Work Products will be separated by division - so that there is a drawer for RD work and another drawer for PRD work. Final Work Products in each of these drawers will be sorted alphabetically by Chemical Name.

Please contact **Records Center Management** via email if you need assistance.

Sharlita Harris
Information Management and Contract Support Branch
Health Effects Division (Mail Code 7509P)
Office of Pesticide Programs US EPA
(703) 308-8147

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: December 19, 2013

SUBJECT: Warfarin – Human Health Risk Assessment of the Requested Experimental Use Permit to Control Feral hogs.

PC Code: 086002
Decision Nos.: 479666
Risk Assessment Type: Single Chemical

Petition No.: None
TXR No.: NA
MRID No.: None

DP Barcodes: D413046
Registration Nos.: 72500-EUP-E
Regulatory Action: Experimental Use Permit
Case No.: NA
CAS No.: 81-81-2
40 CFR: NA

FROM: Mohsen Sahafeyan, Chemist/Risk Assessor
Monica Hawkins, Ph.D., Environmental Health Scientist/ORE Assessor
Yung Yang, Ph.D., Toxicologist
Risk Assessment Branch VI
Health Effects Division (7509P)

THROUGH: Jeffrey Dawson, Acting Branch Chief
Registration Action Branch 6 (RAB6)
Health Effects Division (HED, 7509P)

TO: William Jacobs, Ph.D., Risk Manager Reviewer
Insecticide/Rodenticide Branch
Registration Division

I. CONCLUSIONS

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk was not quantitatively considered since there is no expectation of exposures from drinking water, dietary food, and potential non-dietary sources of exposure, due to provisions made on the proposed label and the restrictions

associated with this research. The HED has no objection to granting the proposed EUP to test the field efficacy of Kaput® Feral Hog Bait to control feral hog populations. HED agrees with the special constraints that are contained within Section G (Proposed Experimental Program) of the EUP study. The registrant is advised that, when the results of the EUP study are presented to the Agency, the submission should include supplemental information related to the HogHopper and how it excludes non-target species. Such information would be critical to estimating how the dispenser prevents accidental exposures to small children, for example.

II. BACKGROUND INFORMATION

Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin] is registered for use as a rodenticide. There are currently no established tolerances for residues of warfarin in food or feed. Scimetrics Ltd. Corporation has submitted an application for an Experimental Use Permit (EUP) for the purpose of testing the field efficacy of Kaput® Feral Hog Bait (1-ounce bait blocks containing 0.005% warfarin; EPA Experimental Use Permit No. 72500-EUP-E) for controlling feral hog populations with a HogHopper feeder or a similar feeder (http://www.feralscan.org.au/docs/HogHopper_Brochure.pdf).

The study will be conducted in the state of Texas in a fenced area, no bigger than 2,471 acres (10 km^2). The total amount of the bait applied will not exceed 10,000 pounds (i.e., if 10,000 pounds bait are used a total of 0.5 lb warfarin would be applied). As part of the EUP research, all the test animals that consume the test product will be sampled to determine the residue levels. Based on previous work, the applicant expects 100% efficacy when feral hogs feed on the bait containing 0.005% warfarin for 5 days, and the low concentration of warfarin along with the requirement of multiple dosing is expected to reduce risk to non-target animals. The bait stations will be continuously monitored by motion-detected cameras, as an attempt to try to monitor feral hog feeding activity and to better understand how non-target animals attempt to gain access to the bait.

III. RESULTS AND DISCUSSION

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk was not quantitatively considered since there is no expectation of exposures from drinking water, food, and other potential non-dietary sources of exposure, due to provisions made on the label. HED is granting the use of warfarin in this EUP for controlling feral hogs as described in the draft label for the product "Kaput® Feral Hog Bait".

Use Directions: Based on the proposed EUP label, the Kaput® Feral Hog Bait product will be used only to control feral hogs on rangeland, forests, non-crop areas, and crop lands. The product is formulated as a bait block that will be added to each HOGHOPPER feeder or similar feeder with a heavy lid that prevents non-target animals from accessing the bait. The bait is a paraffin-containing 1-ounce bait block. The label specifies that the bait is not to be applied on the ground. The label also specifies to "apply

bait in fenced areas and avoid application in open range areas". The Kaput Feral Hog Bait label clearly directs handlers to "wear protective gloves when handling bait or animal carcasses". Twenty-five to one hundred pounds of the bait will be placed into each feeder. The HogHopper delivery system is designed to limit bait access to feral hogs and prevent other species such as livestock from accessing it. Treatment should continue for ten to twenty-one days. The feeder will be monitored and refilled as needed, approximately every two to five days, depending on the number of feral hogs that visit the feeder. The label instructs the applicators to "return to the treatment site within 4 days of application and at a 2-5 day intervals thereafter to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface."

Hazard Identification/Toxicology: No acceptable Guideline toxicity studies on warfarin are available except for acute toxicity submissions. However, based on the availability and completeness of information which pertains directly to humans given the broad use of warfarin as a pharmaceutical and for rodent control, animal toxicology studies are not required for warfarin at this time.

Warfarin, a synthetic analogue of vitamin K, is a member of the coumarin family of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of individuals with hyper-coagulation problems. Its toxicity, mechanism of action, and treatment of overdose in humans are well established.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the vitamin K dependent clotting factors, II, VII, IX and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematomas, uterine bleeding in women, epistaxis and gingival bleeding. Death follows excessive external and/or internal bleeding.

Technical grade warfarin has high acute toxicity *via* oral or inhalation (dust aerosol) routes of exposure (Toxicity Category I) and low acute toxicity *via* dermal route (Toxicity Category III). It is not an eye or skin irritant. There was no skin hypersensitive study available; however, human data indicate s that warfarin does not induce allergic reaction. Warfarin has clearly been established as a human teratogen at clinical doses. Birth defects have been observed as a result of exposure to coumarin anticoagulants during any trimester of pregnancy.

Residue Chemistry: No residue chemistry data are required for the purpose of this limited EUP use of warfarin. The label specifies that the bait not be applied on the ground. The label also specifies to "apply bait in fenced areas and avoid application in open range areas". However, based on the use profile for warfarin in/on rangeland, forests, non-crop areas, and crop lands where livestock exposure cannot be monitored or prevented, if a future registration of this use is sought, data on livestock, as set forth in OPPTS residue chemistry test guidelines 860 series may be required if it cannot be demonstrated that the delivery system prevents exposure to livestock.

Dietary Exposure: Negligible dietary exposure is expected as a result of this EUP use. Possible routes of dietary exposures would be through consumption of poisoned feral hogs or livestock which may feed on the bait. However, the chance of affected feral hogs or livestock being consumed as food are minimal due to the requirement of multiple dosages to achieve efficacy in feral hogs, the staining of tissues of animals which fed on the bait, and the retrieval and consumption of impacted animals. Warfarin is strictly a non-food use rodenticide; and, based on its physicochemical properties, no measureable concentrations of warfarin are expected in drinking water.

Residential Handler and Post-Application Exposure

Residential exposures are not anticipated with the conduct of the research proposed under this proposed EUP; therefore, no residential handler or post-application exposures have been identified or considered in this evaluation of the EUP. This EUP will be conducted in a fenced research facility that will prevent residential exposure such as a child ingesting the bait. Additionally, the HogHopper feeder is designed to limit bait access to feral hogs and prevent other species such as livestock from accessing it. In order for a human to achieve a therapeutic dose, an individual would have to ingest about 1.5 grams of a 0.005% warfarin 1-ounce bait block (i.e., 28.4 grams total weight). If a 10 kg child were to ingest 5 grams of bait (about $1/5^{th}$ of a block), the dose consumed by the child would be 0.025 mg/kg, which is 0.8% of the rat oral LD_{50} of 3 mg/kg for warfarin.

Occupational Handler and Post-Application Exposure: The exposure due to mixing and loading is expected to be negligible because the bait is a paraffin-containing 1- ounce block. The label clearly states "wear protective gloves when handling bait or animal carcasses". Therefore, minimal exposure is expected since no aerosols are created during handling and dermal exposure limited by the use of gloves. HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide. In the case of warfarin, there is a negligible potential for post-application dermal exposure to workers, again because of the use of gloves when handling impacted animal carcasses. Given these considerations, a quantitative occupational handler and post-application exposure assessment was not completed; and it can be concluded that occupational exposures to Kaput® Feral Hog Bait do not pose a significant human health risk under the proposed uses outlined in this EUP.

Jacobs, William

From: Hawkins, Monica
Sent: Thursday, December 19, 2013 10:26 AM
To: Jacobs, William
Cc: Hawkins, Monica; Dawson, Jeffrey
Subject: Warfarin EUP - Courtesy Copy
Attachments: D413046mem.docx

Hi Bill,

Attached is a courtesy copy of the warfarin EUP. I just submitted it through the purple folder process so hopefully you will receive it tomorrow or Monday.

Thank You,

MONICA HAWKINS, PH.D., M.P.H.
U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
RISK ASSESSMENT BRANCH VI
(703)305-6459
HAWKINS.MONICA@EPA.GOV

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: December 19, 2013

SUBJECT: Warfarin – Human Health Risk Assessment of the Requested Experimental Use Permit to Control Feral hogs.

PC Code: 086002
Decision Nos.: 479666
Risk Assessment Type: Single Chemical

Petition No.: None
TXR No.: NA
MRID No.: None

DP Barcodes: D413046
Registration Nos.: 72500-EUP-E
Regulatory Action: Experimental Use Permit
Case No.: NA
CAS No.: 81-81-2
40 CFR: NA

FROM: Mohsen Sahafeyan, Chemist/Risk Assessor
Monica Hawkins, Ph.D., Environmental Health Scientist/ORE Assessor
Yung Yang, Ph.D., Toxicologist
Risk Assessment Branch VI
Health Effects Division (7509P)

THROUGH: Jeffrey Dawson, Acting Branch Chief
Registration Action Branch 6 (RAB6)
Health Effects Division (HED, 7509P)

TO: William Jacobs, Ph.D., Risk Manager Reviewer
Insecticide/Rodenticide Branch
Registration Division

I. CONCLUSIONS

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk was not quantitatively considered since there is no expectation of exposures from drinking water, dietary food, and potential non-dietary sources of exposure, due to provisions made on the proposed label and the restrictions

associated with this research. The HED has no objection to granting the proposed EUP to test the field efficacy of Kaput® Feral Hog Bait to control feral hog populations. HED agrees with the special constraints that are contained within Section G (Proposed Experimental Program) of the EUP study. The registrant is advised that, when the results of the EUP study are presented to the Agency, the submission should include supplemental information related to the HogHopper and how it excludes non-target species. Such information would be critical to estimating how the dispenser prevents accidental exposures to small children, for example.

II. BACKGROUND INFORMATION

Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin] is registered for use as a rodenticide. There are currently no established tolerances for residues of warfarin in food or feed. Scimetrics Ltd. Corporation has submitted an application for an Experimental Use Permit (EUP) for the purpose of testing the field efficacy of Kaput® Feral Hog Bait (1-ounce bait blocks containing 0.005% warfarin; EPA Experimental Use Permit No. 72500-EUP-E) for controlling feral hog populations with a HogHopper feeder or a similar feeder (http://www.feralscan.org.au/docs/HogHopper_Brochure.pdf).

The study will be conducted in the state of Texas in a fenced area, no bigger than 2,471 acres (10 km^2). The total amount of the bait applied will not exceed 10,000 pounds (i.e., if 10,000 pounds bait are used a total of 0.5 lb warfarin would be applied). As part of the EUP research, all the test animals that consume the test product will be sampled to determine the residue levels. Based on previous work, the applicant expects 100% efficacy when feral hogs feed on the bait containing 0.005% warfarin for 5 days, and the low concentration of warfarin along with the requirement of multiple dosing is expected to reduce risk to non-target animals. The bait stations will be continuously monitored by motion-detected cameras, as an attempt to try to monitor feral hog feeding activity and to better understand how non-target animals attempt to gain access to the bait.

III. RESULTS AND DISCUSSION

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk was not quantitatively considered since there is no expectation of exposures from drinking water, food, and other potential non-dietary sources of exposure, due to provisions made on the label. HED is granting the use of warfarin in this EUP for controlling feral hogs as described in the draft label for the product "Kaput® Feral Hog Bait".

Use Directions: Based on the proposed EUP label, the Kaput® Feral Hog Bait product will be used only to control feral hogs on rangeland, forests, non-crop areas, and crop lands. The product is formulated as a bait block that will be added to each HOGHOPPER feeder or similar feeder with a heavy lid that prevents non-target animals from accessing the bait. The bait is a paraffin-containing 1-ounce bait block. The label specifies that the bait is not to be applied on the ground. The label also specifies to "apply

bait in fenced areas and avoid application in open range areas". The Kaput Feral Hog Bait label clearly directs handlers to "wear protective gloves when handling bait or animal carcasses". Twenty-five to one hundred pounds of the bait will be placed into each feeder. The HogHopper delivery system is designed to limit bait access to feral hogs and prevent other species such as livestock from accessing it. Treatment should continue for ten to twenty-one days. The feeder will be monitored and refilled as needed, approximately every two to five days, depending on the number of feral hogs that visit the feeder. The label instructs the applicators to "return to the treatment site within 4 days of application and at a 2-5 day intervals thereafter to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface."

Hazard Identification/Toxicology: No acceptable Guideline toxicity studies on warfarin are available except for acute toxicity submissions. However, based on the availability and completeness of information which pertains directly to humans given the broad use of warfarin as a pharmaceutical and for rodent control, animal toxicology studies are not required for warfarin at this time.

Warfarin, a synthetic analogue of vitamin K, is a member of the coumarin family of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of individuals with hyper-coagulation problems. Its toxicity, mechanism of action, and treatment of overdose in humans are well established.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the vitamin K dependent clotting factors, II, VII, IX and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematomas, uterine bleeding in women, epistaxis and gingival bleeding. Death follows excessive external and/or internal bleeding.

Technical grade warfarin has high acute toxicity *via* oral or inhalation (dust aerosol) routes of exposure (Toxicity Category I) and low acute toxicity *via* dermal route (Toxicity Category III). It is not an eye or skin irritant. There was no skin hypersensitive study available; however, human data indicate s that warfarin does not induce allergic reaction. Warfarin has clearly been established as a human teratogen at clinical doses. Birth defects have been observed as a result of exposure to coumarin anticoagulants during any trimester of pregnancy.

Residue Chemistry: No residue chemistry data are required for the purpose of this limited EUP use of warfarin. The label specifies that the bait not be applied on the ground. The label also specifies to "apply bait in fenced areas and avoid application in open range areas". However, based on the use profile for warfarin in/on rangeland, forests, non-crop areas, and crop lands where livestock exposure cannot be monitored or prevented, if a future registration of this use is sought, data on livestock, as set forth in OPPTS residue chemistry test guidelines 860 series may be required if it cannot be demonstrated that the delivery system prevents exposure to livestock.

Dietary Exposure: Negligible dietary exposure is expected as a result of this EUP use. Possible routes of dietary exposures would be through consumption of poisoned feral hogs or livestock which may feed on the bait. However, the chance of affected feral hogs or livestock being consumed as food are minimal due to the requirement of multiple dosages to achieve efficacy in feral hogs, the staining of tissues of animals which fed on the bait, and the retrieval and consumption of impacted animals. Warfarin is strictly a non-food use rodenticide; and, based on its physicochemical properties, no measureable concentrations of warfarin are expected in drinking water.

Residential Handler and Post-Application Exposure

Residential exposures are not anticipated with the conduct of the research proposed under this proposed EUP; therefore, no residential handler or post-application exposures have been identified or considered in this evaluation of the EUP. This EUP will be conducted in a fenced research facility that will prevent residential exposure such as a child ingesting the bait. Additionally, the HogHopper feeder is designed to limit bait access to feral hogs and prevent other species such as livestock from accessing it. In order for a human to achieve a therapeutic dose, an individual would have to ingest about 1.5 grams of a 0.005% warfarin 1-ounce bait block (i.e., 28.4 grams total weight). If a 10 kg child were to ingest 5 grams of bait (about $1/5^{th}$ of a block), the dose consumed by the child would be 0.025 mg/kg, which is 0.8% of the rat oral LD_{50} of 3 mg/kg for warfarin.

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Jacobs, William

From: Jacobs, William
Sent: Wednesday, December 18, 2013 11:37 AM
To: Hawkins, Monica
Cc: Sahafeyan, Mohsen
Subject: RE: Warfarin EUP
Attachments: WarfarinEUP-12-18-13 (2)-WWJcomments-121813.docx

I have read through this item. Here (attached) is a version with minor edits and comments included.

From: Hawkins, Monica
Sent: Wednesday, December 18, 2013 9:22 AM
To: Jacobs, William
Cc: Sahafeyan, Mohsen; Dawson, Jeffrey
Subject: Warfarin EUP

Hi Bill,

As I stated on the telephone a few minutes ago Jeff Dawson made some track changes after I emailed you the document earlier this morning. Please review this latest draft document, edit it and then email it back to Mohsen and myself for the purple folder process.

Thank You,

MONICA HAWKINS, PH.D., M.P.H.
U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
RISK ASSESSMENT BRANCH VI
(703)305-6459
HAWKINS.MONICA@EPA.GOV

Comments by Bill Jacobs (12/18/13)
Suggested additions are in boldface.
~~Suggested deletions are in Strikethrough.~~
[General comments – not for inclusion – are in bracketed italics.]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: December 18, 2013

SUBJECT: Warfarin – Human Health Risk Assessment of the Requested Experimental Use Permit to Control Feral hogs.

PC Code: 086002
Decision Nos.: 479666
Risk Assessment Type: Single Chemical

DP Barcodes: D413046
Registration Nos.: 72500-EUP-E
Regulatory Action: Experimental Use Permit

Petition No.: None
TXR No.: NA
MRID No.: None

Case No.: NA
CAS No.: 81-81-2
40 CFR: NA

FROM: Mohsen Sahafeyan, Chemist/Risk Assessor
Monica Hawkins, Ph.D., Environmental Health Scientist
Yung Yang, Ph.D., Toxicologist
Risk Assessment Branch VI
Health Effects Division (7509P)

THROUGH: Jeffrey Dawson, Acting Branch Chief
Registration Action Branch 6 (RAB6)
Health Effects Division (HED, 7509P)

TO: William Jacobs, **Ph.D.,** Risk Manager Reviewer
Insecticide/Rodenticide Branch
Registration Division

I. CONCLUSIONS

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk was not quantitatively considered since there is no expectation of exposures from drinking water, dietary food, and potential non-dietary sources of exposure, due to provisions made on the proposed label and the restrictions associated with this research. The HED has no objection to granting the proposed EUP to test the field efficacy of Kaput® Feral Hog Bait to control feral hog populations. HED agrees with the special constraints that are contained within Section G (Proposed Experimental Program) of the EUP study. The registrant is advised that, when the results of the EUP study are presented to the Agency, **the submission should include** supplemental information related to the HogHopper and how it excludes non-target species. **Such information would be** ~~should be included which is~~ critical ~~in~~ **to** estimating how **the dispenser** ~~it~~ prevents accidental exposures to small children, for example.

II. BACKGROUND INFORMATION

Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin] is registered for use as a rodenticide. There are currently no established tolerances for residues of warfarin in food or feed. Scimetrics Ltd. Corporation has submitted an application for an Experimental Use Permit (EUP) for the purpose of testing the field efficacy of Kaput® Feral Hog Bait (1-ounce bait blocks containing 0.005% warfarin; EPA Experimental Use Permit No. 72500-EUP-E) for controlling feral hog populations with a HogHopper feeder or a similar feeder (http://www.feralscan.org.au/docs/HogHopper_Brochure.pdf).

The study will be conducted in the state of Texas in a fenced area, no bigger than 2,471 acres (10 km^2). The total amount of the bait applied will not exceed 10,000 pounds (i.e., if 10,000 pounds bait are used a total of 0.5 lb warfarin would be applied). As part of the EUP research, all the test animals that consume the test product will be sampled to determine the residue levels. Based on previous work, **the applicant expects** *[I don't!]* 100% efficacy ~~is expected~~ when feral hogs ~~are fed~~ **feed** on the bait containing 0.005% warfarin for 5 days, and the low concentration of warfarin along with the requirement of multiple dosing ~~will also~~ **is expected** *[by registrant and EPA]* **to** reduce risk to non-target animals. The bait stations will be continuously monitored by motion-detected cameras, as an attempt to try to monitor feral hog feeding activity and to better understand how non-target animals attempt to gain access to the bait.

III. RESULTS AND DISCUSSION

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk was not quantitatively considered since there is no expectation of exposures from drinking water, food, and other potential non-dietary sources of exposure, due to provisions made on the label. HED **is** granting the use of warfarin in this EUP for controlling feral hogs as described in the draft label for the product "Kaput® Feral Hog Bait".

Use Directions: Based on the proposed EUP label, the Kaput® Feral Hog Bait product will be used **only** to control ~~only~~ feral hogs on rangeland, forests, non-crop areas, and crop lands. The product is formulated as a bait block that will be added to each HOGHOPPER feeder or similar feeder with a heavy lid that prevents non-target animals from accessing the bait. The bait is a paraffin-containing 1-ounce bait block. The label specifies that the bait **is** not to be applied on the ground. ~~It~~ **The label** also specifies to "apply bait in fenced areas and avoid application in open range areas". The Kaput Feral Hog Bait label clearly directs handlers to "wear protective gloves when handling bait or animal carcasses". Twenty-five to one hundred pounds of the bait will be placed into each feeder. The HogHopper delivery system is designed to limit ~~the~~ **bait** access to feral hogs and prevent other species such as livestock from accessing it. Treatment should continue for ten to twenty-one days. The feeder will be monitored and refilled as needed, approximately every two to five days, depending on the number of feral hogs that visit the feeder. The label instructs the applicators to "return to the treatment site within 4 days of application and at a 2-5 day intervals thereafter to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface."

Hazard Identification/Toxicology: No acceptable Guideline toxicity studies on warfarin are available except for acute toxicity submissions. However, based on the availability and completeness of information which pertains directly to humans given the broad use of warfarin as a pharmaceutical and for rodent control, animal toxicology studies are not required for warfarin at this time.

Warfarin, a synthetic analogue of vitamin K, is a member of the coumarin family of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of individuals with hyper-coagulation problems. Its toxicity, mechanism of action, and treatment of overdose in humans are well established.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the vitamin K dependent clotting factors, II, VII, IX and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematomas, uterine bleeding in women, epistaxis and gingival bleeding. Death follows excessive external and/or internal bleeding.

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open range areas". However, based on the use profile for warfarin in/on rangeland, forests, non-crop areas, and crop lands where livestock exposure cannot be monitored or prevented, if a future registration of this use is sought, data on livestock, as set forth in OPPTS residue chemistry test guidelines 860 series may be required if it cannot be demonstrated **that** the delivery system prevents exposure to livestock.

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Jacobs, William

From: Hawkins, Monica
Sent: Wednesday, December 18, 2013 9:22 AM
To: Jacobs, William
Cc: Sahafeyan, Mohsen; Dawson, Jeffrey
Subject: Warfarin EUP
Attachments: WarfarinEUP-12-18-13.docx

Hi Bill,

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Thank You,

MONICA HAWKINS, PH.D., M.P.H.
U.S. ENVIRONMENTAL PROTECTION AGENCY
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: December 18, 2013

SUBJECT: Warfarin – Human Health Risk Assessment of the Requested Experimental Use Permit to Control Feral hogs.

PC Code: 086002
Decision Nos.: 479666
Risk Assessment Type: Single Chemical

Petition No.: None
TXR No.: NA
MRID No.: None

DP Barcodes: D413046
Registration Nos.: 72500-EUP-E
Regulatory Action: Experimental Use Permit
Case No.: NA
CAS No.: 81-81-2
40 CFR: NA

FROM: Mohsen Sahafeyan, Chemist/Risk Assessor
Monica Hawkins, Ph.D., Environmental Health Scientist
Yung Yang, Ph.D., Toxicologist
Risk Assessment Branch VI
Health Effects Division (7509P)

THROUGH: Jeffrey Dawson, Acting Branch Chief
Registration Action Branch 6 (RAB6)
Health Effects Division (HED, 7509P)

TO: William Jacobs, Risk Manager Reviewer
Insecticide/Rodenticide Branch
Registration Division

I. CONCLUSIONS

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk was not quantitatively considered since there is no expectation of exposures from drinking water, dietary food, and potential non-dietary sources of exposure, due to provisions made on the proposed label and the restrictions

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Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin] is registered for use as a rodenticide. There are currently no established tolerances for residues of warfarin in food or feed. Scimetrics Ltd. Corporation has submitted an application for an Experimental Use Permit (EUP) for the purpose of testing the field efficacy of Kaput® Feral Hog Bait (1 ouncebait blocks containing 0.005% warfarin; EPA Experimental Use Permit No. 72500-EUP-E) for controlling feral hog populations with a HogHopper feeder or a similar feeder (http://www.feralscan.org.au/docs/HogHopper_Brochure.pdf).

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III. RESULTS AND DISCUSSION

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Use Directions: Based on the proposed EUP label, the Kaput® Feral Hog Bait product will be used to control only feral hogs on rangeland, forests, non-crop areas, and crop lands. The product is formulated as a bait block that will be added to each HOGHOPPER feeder or similar feeder with a heavy lid that prevents non-target animals from accessing the bait. The bait is a paraffin-containing 1-ounce bait block. The label specifies that the bait not to be applied on the ground. It also specifies to "apply bait in fenced areas and avoid application in open range areas". The Kaput Feral Hog Bait label

clearly directs handlers to "wear protective gloves when handling bait or animal carcasses". Twenty-five to one hundred pounds of the bait will be placed into each feeder. The HogHopper delivery system is designed to limit the access to feral hogs and prevent other species such as livestock from accessing it. Treatment should continue for ten to twenty-one days. The feeder will be monitored and refilled as needed, approximately every two to five days, depending on the number of feral hogs that visit the feeder. The label instructs the applicators to "return to the treatment site within 4 days of application and at a 2-5 day intervals thereafter to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface."

Hazard Identification/Toxicology: No acceptable Guideline toxicity studies on warfarin are available except for acute toxicity submissions. However, based on the availability and completeness of information which pertains directly to humans given the broad use of warfarin as a pharmaceutical and for rodent control, animal toxicology studies are not required for warfarin at this time.

Warfarin, a synthetic analogue of vitamin K, is a member of the coumarin family of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of individuals with hyper-coagulation problems. Its toxicity, mechanism of action, and treatment of overdose in humans are well established.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the vitamin K dependent clotting factors, II, VII, IX and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematomas, uterine bleeding in women, epistaxis and gingival bleeding. Death follows excessive external and/or internal bleeding.

Technical grade warfarin has high acute toxicity *via* oral or inhalation (dust aerosol) routes of exposure (Toxicity Category I) and low acute toxicity *via* dermal route (Toxicity Category III). It is not an eye or skin irritant. There was no skin hypersensitive study available; however, human data indicates that warfarin does not induce allergic reaction. Warfarin has clearly been established as a human teratogen at clinical doses. Birth defects have been observed as a result of exposure to coumarin anticoagulants during any trimester of pregnancy.

Residue Chemistry: No residue chemistry data are required for the purpose of this limited EUP use of warfarin. The label specifies that the bait not be applied on the ground. It also specifies to "apply bait in fenced areas and avoid application in open range areas". However, based on the use profile for warfarin in/on rangeland, forests, non-crop areas, and crop lands where livestock exposure cannot be monitored or prevented, if a future registration of this use is sought, data on livestock, as set forth in OPPTS residue chemistry test guidelines 860 series may be required if it cannot be demonstrated the delivery system prevents exposure to livestock.

Dietary Exposure: Negligible dietary exposure is expected as a result of this EUP use. Possible routes of dietary exposures would be through consumption of poisoned feral

hogs or livestock which may feed on the bait. However, the chance of affected feral hogs or livestock being consumed as food are minimal due to the requirement of multiple dosages to achieve efficacy in feral hogs, staining of tissues of animals which fed on the bait, and the retrieval and consumption of impacted animals. Warfarin is strictly a non-food use rodenticide and since, based on its physicochemical properties, no measureable concentrations of warfarin are expected in drinking water.

Residential Handler and Post-Application Exposure

Residential exposures are not anticipated with the conduct of the research proposed under this proposed EUP; therefore, there are no residential handler or post-application exposures have been identified or considered in this evaluation of the EUP. This EUP will be conducted in a fenced research facility that will prevent residential exposure such as a child ingesting the bait. Additionally, the HogHopper feeder is designed to limit the access to feral hogs and prevent other species such as livestock from accessing it. In order for a human to achieve a therapeutic dose, an individual would have to ingest about 1.5 grams of a 0.005% warfarin 1- ounce bait block (i.e., 28.4 grams total weight). If a 10 kg child were to ingest 5 grams of bait (about $1/5^{th}$ of a block), the dose consumed by the child would be 0.025 mg/kg, which is 0.8% of the rat oral LD_{50} of 3 mg/kg for warfarin.

Occupational Handler and Post-Application Exposure: The exposure due to mixing and loading is expected to be negligible because the bait is a paraffin-containing 1- ounce block. The label clearly states "wear protective gloves when handling bait or animal carcasses". Therefore, minimal exposure is expected since no aerosols are created during handling and dermal exposure limited by the use of gloves. HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide. In the case of warfarin, there is a negligible potential for post-application dermal exposure to workers again because of the use of gloves when handling impacted animal carcasses. Given these considerations, a quantitative occupational handler and post-application exposure assessment was not completed and it can be concluded that occupational exposures to Kaput® Feral Hog Bait do not pose a significant human health risk under the proposed uses outlined in this EUP.

Jacobs, William

From: Hawkins, Monica
Sent: Wednesday, December 18, 2013 8:17 AM
To: Jacobs, William
Cc: Hawkins, Monica; Dawson, Jeffrey
Subject: Warfarin EUP
Attachments: WarfarinEUP-12-18-13.docx

Hi Bill,

I've attached the warfarin EUP as a draft for you. Please review and edit the document and then email it back to me. We want you to review the document so that you can let us know if the document meets your needs before it is finalized.

Just a reminder that I will be in the office today and tomorrow until 3:30 PM if you want me to purple folder it by tomorrow before I leave for the day. I will be out of the office from December 23, 2013 – January 3, 2014.

Jeff Dawson is my Acting Branch Chief this week and Donna Davis will begin on December 29th.

Thank You,

MONICA HAWKINS, PH.D., M.P.H.
U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
RISK ASSESSMENT BRANCH VI
(703)305-6459
HAWKINS.MONICA@EPA.GOV

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: December 13, 2013

SUBJECT: Warfarin – Human Health Risk Assessment of the Requested Experimental Use Permit to Control Feral hogs.

PC Code: 086002
Decision Nos.: 479666
Risk Assessment Type: Single Chemical, Aggregate
Petition No.: None
TXR No.: NA
MRID No.: None

DP Barcodes: D413046
Registration Nos.: 72500-EUP-E
Regulatory Action: Experimental Use Permit
Case No.: NA
CAS No.: 81-81-2
40 CFR: NA

FROM: Mohsen Sahafeyan, Chemist/Risk Assessor
Monica Hawkins, Ph.D., Environmental Health Scientist
Yung Yang, Ph.D., Toxicologist
Risk Assessment Branch VI
Health Effects Division (7509P)

THROUGH: Jeffrey Dawson, Acting Branch Chief
Registration Action Branch 6 (RAB6)
Health Effects Division (HED, 7509P)

TO: William Jacobs, Risk Manager Reviewer
Insecticide/Rodenticide Branch
Registration Division

I. CONCLUSIONS

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk estimates should be minimal if any since there is no expectation of exposures from drinking water, dietary food, and non-dietary sources, due to provisions made on the label. The HED has no objection to granting the proposed

EUP to test the field efficacy of Kaput® Feral Hog Bait to control feral hog populations. HED agrees with the special concerns that are contained within Section G (Proposed Experimental Program) of the EUP study. The registrant is advised that when the results of the EUP study are presented to the Agency supplemental information related to the HogHopper and how it excludes non-target species should be included.

II. BACKGROUND INFORMATION

Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin] is registered for use as a rodenticide. There are currently no established tolerances for residues of warfarin in food or feed. Scimetrics Ltd. Corporation has submitted an application for an Experimental Use Permit (EUP) for the purpose of testing the field efficacy of Kaput® Feral Hog Bait (a bait block containing 0.005% warfarin; EPA Experimental Use Permit No. 72500-EUP-E) for controlling feral hog populations with a HogHopper feeder or a similar feeder (http://www.feralscan.org.au/docs/HogHopper_Brochure.pdf).

The study will be conducted in the state of Texas in a fenced area, no bigger than 2,471 acres (10 km^2). The total amount of the bait applied will not exceed 10,000 pounds. As part of the EUP study, all the test animals that consume the test product will be sampled to determine the residue levels. Based on previous work, the company claims that 100% efficacy is expected when feral hogs are fed on the bait containing 0.005% warfarin for 5 days and the low concentration of warfarin along with the requirement of multiple dosing will also reduce risk to non-target animals. The bait stations will be continuously monitored by motion-detected cameras, as an attempt to try and limit non-target animals from gaining access to the bait.

III. RESULTS AND DISCUSSION

HED has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk estimates should be minimal if any since there is no expectation of exposures from drinking water, dietary food, and non-dietary sources, due to provisions made on the label. HED recommends in favor of granting the use of warfarin in this EUP for controlling feral hogs as described in the draft label for the product "Kaput® Feral Hog Bait".

Use Directions: Based on the proposed EUP label, the Kaput® Feral Hog Bait product will be used to control only feral hogs on rangeland, forests, non-crop areas, and crop lands. The product is formulated as a bait block that will be added to each HOGHOPPER feeder or similar feeder with a heavy lid that prevents non-target animals from accessing the bait. The bait is a paraffin-containing 1-ounce bait block. The label specifies that the bait not to be applied on the ground. It also specifies to "apply bait in fenced areas and avoid application in open range areas". The Kaput Feral Hog Bait label clearly directs handlers to "wear protective gloves when handling bait or animal carcasses". Twenty-five to one hundred pounds of the bait will be placed into each feeder. The HogHopper delivery system is designed to limit the access to feral hogs and

prevent other species such as livestock from accessing it. Treatment should continue for ten to twenty-one days. The feeder will be monitored and refilled as needed, approximately every two to five days, depending on the number of feral hogs that visit the feeder. The label instructs the applicators to "return to the treatment site within 4 days of application and at a 2-5 day intervals thereafter to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface."

Hazard Identification/Toxicology: No acceptable Guideline toxicity studies on warfarin are available except for acute toxicity submissions. However, based on the availability and completeness of the human information, animal toxicology studies are not required for warfarin at this time. If a future registration of this use is sought, based upon designation as a food or non-food use, additional data may be required to fulfill the revised 2007 40 CFR Part 158 Toxicology Data Requirements.

Warfarin, a synthetic analogue of vitamin K, is a member of the coumarin family of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of individuals with hyper-coagulation problems. Its toxicity, mechanism of action, and treatment of overdose in humans are well established.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the vitamin K dependent clotting factors, II, VII, IX and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematomas, uterine bleeding in women, epistaxis and gingival bleeding. Death follows excessive external and/or internal bleeding.

Technical grade warfarin has high acute toxicity *via* oral or inhalation (dust aerosol) routes of exposure (Toxicity Category I) and low acute toxicity *via* dermal route (Toxicity Category III). It is not an eye or skin irritant. There was no skin hypersensitive study available; however, human data indicates that warfarin does not induce allergic reaction. Warfarin has clearly been established as a human teratogen at clinical doses. Birth defects have been observed as a result of exposure to coumarin anticoagulants during any trimester of pregnancy.

Residue Chemistry: No residue chemistry data are required for the purpose of this limited EUP use of warfarin. The label specifies that the bait not be applied on the ground. It also specifies to "apply bait in fenced areas and avoid application in open range areas". However, based on the use profile for warfarin in/on rangeland, forests, non-crop areas, and crop lands where livestock exposure cannot be monitored or prevented, if a future registration of this use is sought, data on livestock, as set forth in OPPTS residue chemistry test guidelines 860 series may be required.

Dietary Exposure: Negligible dietary exposure is expected as a result of this EUP use. Possible routes of dietary exposures would be through feral hogs or livestock which may feed on the bait. However, the chance of affected feral hogs or livestock being consumed as food are minimal due to the requirement of multiple dosages, staining of tissues of animals which fed on the bait, and the retrieval of animal carcasses. Warfarin is strictly a

non-food use rodenticide and since, based on its physicochemical properties, no measureable concentrations of warfarin are expected in drinking water. If a future registration of this use is sought, data may be required as described under residue chemistry section above and HED will reevaluate dietary exposure.

Residential Handler and Post-Application Exposure

There are no residential uses proposed for the EUP; therefore, there are no residential handler or post-application exposures associated with the EUP. This EUP will be conducted in a fenced research facility that will prevent any or most residential exposure such as a child ingesting the bait. Additionally, the HogHopper feeder is designed to limit the access to feral hogs and prevent other species such as livestock from accessing it. In order for a human to achieve a therapeutic dose, an individual would have to ingest about 1.5 grams out of 28.4 grams of a 1- ounce bait block (0.005% warfarin). If a 10 kg child were to ingest 5 grams of bait, the dose consumed by the child would be 0.025 mg/kg, which is 0.8% of the rat oral LD_{50} of 3 mg/kg for warfarin.

Occupational Handler and Post-Application Exposure: The exposure due to mixing and loading is expected to be minimal because the bait is a paraffin-containing 1- ounce bait block. Therefore, minimal inhalation exposure is expected. At this time, no toxicological points of departure have been established for warfarin. HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide. In the case of warfarin, there is a minimal potential for post-application dermal exposure to workers since the label clearly states "wear protective gloves when handling bait or animal carcasses". A quantitative occupational handler and post-application exposure assessment does not need to be completed to conclude with reasonable certainty that occupational exposures to Kaput® Feral Hog Bait do not pose a significant human health risk.

Jacobs, William

From: Jacobs, William
Sent: Tuesday, November 26, 2013 12:45 PM
To: Sahafeyan, Mohsen
Subject: RE: warfarin- EUP draft memo
Attachments: WarfarinEUP-11-26-13-WWJcomments.docx

See the attachment, which has my comments inserted in bracketed italics. My comments provide additional information that might slightly alter the assessment, especially in areas relevant to bait particle size. (I don't expect a list of potential future data requirements today.)

Thank again.

From: Sahafeyan, Mohsen
Sent: Tuesday, November 26, 2013 11:47 AM
To: Jacobs, William
Cc: Laws, Meredith
Subject: warfarin- EUP draft memo

Hi Bill,
Here is the draft memo; there is a lingering respirator issue that will be resolved this afternoon. I will not be here after thanksgiving for 3 weeks. I need to know if this memo works for you and if you have any comments before I finalize it COB today. Would you mind taking a look at it and let me know quick; it is only 3 and half pages. Thanks in advance.

Mohsen Sahafeyan
EPA/OPP/HED/RAB6
703-305-0776 (voice)
703-305-0871 (fax)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

JACOBS COMMENTS of 12:50 PM in bracketed italics

MEMORANDUM

Date: 26-NOV-2013

SUBJECT: Warfarin – Human Health Risk Assessment of the Requested Experimental Use Permit to Control Feral hogs.

PC Code: 086002
Decision Nos.: 479666
Risk Assessment Type: Single Chemical, Aggregate
Petition No.: None
TXR No.: NA
MRID No.: None

DP Barcodes: D413046
Registration Nos.: 72500-EUP-E
Regulatory Action: Experimental Use Permit
Case No.: NA
CAS No.: 81-81-2
40 CFR: NA

FROM: Mohsen Sahafeyan, Chemist/Risk Assessor
Monica Hawkins, Ph.D., Environmental Health Scientist
Yung Yang, Ph.D., Toxicologist
Risk Assessment Branch VI
Health Effects Division (7509P)

THROUGH: Jeffrey Dawson, Acting Branch Chief
Registration Action Branch 6 (RAB6)
Health Effects Division (HED, 7509P)

TO: William Jacobs, Risk Manager Reviewer
Insecticide/Rodenticide Branch
Registration Division

Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin] is registered for use as a rodenticide. There are currently no established tolerances for residues of warfarin in food or feed. Scimetrics Ltd. Corporation has submitted an application for an Experimental Use Permit (EUP) for the purpose of testing the field efficacy of Kaput® Feral Hog Bait (granular formulation containing 0.005% warfarin; EPA Experimental Use Permit No. 72500-EUP-E) for controlling feral hog populations.

HED Conclusion

The Health Effects Division (HED) has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk estimates should be minimal if any since there is negligible expectation of exposures from drinking water, dietary food, and non-dietary sources, due to provisions made on the label. HED recommends in favor of granting the use of warfarin in this EUP for controlling feral hogs as described in the draft label for the product "Kaput® Feral Hog Bait". However, if a future registration of this use is sought, additional toxicology, residue chemistry and occupational data may be required. *[At some point, we'll want to prepare the applicant regarding what those requirements are likely to be.]*

Detail Consideration

The study will be conducted in the state of Texas in a fenced area, no bigger than 2,471 acres (10 km^2). The amount of formulated product is not to exceed 12,600 lbs. As part of the EUP study, all the test animals that consume the test product will be sampled to determine the residue levels. *[The animals that consume bait will be free-ranging. Although the bait stations are to be in fenced pastures, the fences will not necessarily contain all exposed animals or allow them to be cornered and collected. The animals most likely to be sampled will be some or all of those that succumb to Warfarin (or die of other causes) within the fenced pastures, which can be enormous in Texas. So, "all" animals probably won't be sampled, but all that they are able to collect might be. EFED is likely to suggest additional procedures for monitoring nontarget species, which seems to me to be a very good idea.]* Based on previous work, the company claims that 100% efficacy is expected when feral hogs are fed on the bait containing 0.005% warfarin for 5 days and the low concentration of warfarin along with the requirement of multiple dosings will also reduce risk to non-target animals. *[I'm not sure that their expectation is realistic, BTW.]* The formulated product contains a blue dye to cause staining of the tissues of the test animals and prevent their consumption. In addition, the bait stations will be continuously monitored by cameras, assuring non-target animals not gaining access to the bait.

Use Directions: The use pattern summary is taken from the Kaput® Feral Hog Bait label that is in the EUP application. The Kaput® Feral Hog Bait product will be used to control only feral hogs on rangeland, forests, non-crop areas, and crop lands. The product is formulated as a granule that will be added to each HOGHOPPER feeder or similar feeder with a heavy lid that prevents non-target animals from accessing the bait. *[The bait is a paraffin-containing 1-oz bait block -- a 1"-X-1"-1" cube, more or less. There likely will be some small fragments but probably few, if any, true fines like would be expected with pelleted or meal baits.]* The label specifies that the bait not to be applied on the ground. It also specifies to "apply bait in fenced areas and avoid application in open range areas". The Kaput Feral Hog Bait label clearly directs handlers to "wear protective gloves when handling bait or animal carcasses". Twenty-five to one hundred pounds of the bait will be placed into each feeder. The animal access door will be closed limiting access to feral

hogs only. Treatment should continue for ten to twenty-one days. The feeder will be monitored and refilled as needed, approximately every two to five days, depending on the number of feral hogs that visit the feeder. The label instructs the applicators to "return to the treatment site within 4 days of application and at a 2-5 day intervals thereafter to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface."

Hazard Identification/Toxicology: No acceptable Guideline toxicity studies on warfarin are available except for acute toxicity submissions. The Agency has based its determinations relative to human safety on human evidence and experience. If a future registration of this use is sought, based upon designation as a food or non-food use, additional data may be required to fulfill the revised 2007 40 CFR Part 158 Toxicology Data Requirements.

Warfarin, a synthetic analogue of vitamin K, is a member of the coumarin family of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of individuals with hyper-coagulation problems. Its toxicity, mechanism of action, and treatment of overdose in humans are well established.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the vitamin K dependent clotting factors, II, VII, IX and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematomas, uterine bleeding in women, epistaxis and gingival bleeding. Death follows excessive external and/or internal bleeding.

Technical grade warfarin has high acute toxicity *via* oral or inhalation (dust aerosol) routes of exposure (Toxicity Category I) and low acute toxicity *via* dermal route (Toxicity Category III). It is not an eye or skin irritant. There was no skin hypersensitive study available; however, human data indicates that warfarin does not induce allergic reaction. Warfarin has clearly been established as a human teratogen at clinical doses. Birth defects have been observed as a result of exposure to coumarin anticoagulants during any trimester of pregnancy.

Residue Chemistry: No residue chemistry data *[are?]* required for the purpose of this limited EUP use of warfarin. However, based on the use profile for warfarin in/on rangeland, forests, non-crop areas, and crop lands where livestock exposure cannot be monitored or prevented, if a future registration of this use is sought, data on livestock, as set forth in OPPTS residue chemistry test guidelines 860 series may be required.

Dietary Exposure: Negligible dietary exposure is expected as a result of this EUP use. Possible routes of dietary exposures would be through feral hogs or livestock which may feed on the bait. However, the chance of affected feral hogs or livestock being consumed as food are minimal due to the requirement of multiple dosages, staining of tissues of animals which fed on the bait, placement of monitoring cameras in each station, and retrieving of animal carcasses *[also the nature of the proposed use (in a monitored experiment)]*. Exposure through drinking water is also expected to be negligible, if any,

for this EUP use since warfarin baits are used off the ground and in limited quantities. If a future registration of this use is sought, data may be required as described under residue chemistry section above and HED will reevaluate dietary exposure.

Occupational Exposure: There is no mixing or loading in the typical sense of most pesticide applications although there is the potential for exposure to occupational handlers who are placing the bait into the feeder. In order to curtail the potential inhalation exposure to workers loading granules HED recommends the use of a respirator. *[Note 1-oz block size.]* However, no toxicological points of departure have been established for warfarin. HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide. In the case of warfarin, there is a minimal potential for post-application dermal exposure to workers since the label clearly states "wear protective gloves when handling bait or animal carcasses". A quantitative occupational handler and post-application exposure assessment does not need to be completed to conclude with reasonable certainty that occupational exposures to Kaput® Feral Hog Bait do not pose a significant human health risk.

Jacobs, William

From: Jacobs, William
Sent: Tuesday, November 26, 2013 11:48 AM
To: Sahafeyan, Mohsen
Subject: RE: warfarin- EUP draft memo

Thank you for this. I will look at it right away.

From: Sahafeyan, Mohsen
Sent: Tuesday, November 26, 2013 11:47 AM
To: Jacobs, William
Cc: Laws, Meredith
Subject: warfarin- EUP draft memo

Hi Bill,
Here is the draft memo; there is a lingering respirator issue that will be resolved this afternoon. I will not be here after thanksgiving for 3 weeks. I need to know if this memo works for you and if you have any comments before I finalize it COB today. Would you mind taking a look at it and let me know quick; it is only 3 and half pages. Thanks in advance.

Mohsen Sahafeyan
EPA/OPP/HED/RAB6
703-305-0776 (voice)
703-305-0871 (fax)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

→ AM DRAFT!

MEMORANDUM

Date: 26-NOV-2013

SUBJECT: Warfarin – Human Health Risk Assessment of the Requested Experimental Use Permit to Control Feral hogs.

PC Code: 086002
Decision Nos.: 479666
Risk Assessment Type: Single Chemical, Aggregate
Petition No.: None
TXR No.: NA
MRID No.: None

DP Barcodes: D413046
Registration Nos.: 72500-EUP-E
Regulatory Action: Experimental Use Permit
Case No.: NA
CAS No.: 81-81-2
40 CFR: NA

FROM: Mohsen Sahafeyan, Chemist/Risk Assessor
Monica Hawkins, Ph.D., Environmental Health Scientist
Yung Yang, Ph.D., Toxicologist
Risk Assessment Branch VI
Health Effects Division (7509P)

THROUGH: Jeffrey Dawson, Acting Branch Chief
Registration Action Branch 6 (RAB6)
Health Effects Division (HED, 7509P)

TO: William Jacobs, Risk Manager Reviewer
Insecticide/Rodenticide Branch
Registration Division

Warfarin [3-(alpha-acetonylbenzyl)-4-hydroxycoumarin] is registered for use as a rodenticide. There are currently no established tolerances for residues of warfarin in food or feed. Scimetrics Ltd. Corporation has submitted an application for an Experimental Use Permit (EUP) for the purpose of testing the field efficacy of Kaput® Feral Hog Bait (granular formulation containing 0.005% warfarin; EPA Experimental Use Permit No. 72500-EUP-E) for controlling feral hog populations.

HED Conclusion

The Health Effects Division (HED) has reviewed the available toxicological, residue chemistry, and occupational/residential exposure information relevant for this assessment. For the purposes of this EUP, aggregate risk estimates should be minimal if any since there is negligible expectation of exposures from drinking water, dietary food, and non-dietary sources, due to provisions made on the label. HED recommends in favor of granting the use of warfarin in this EUP for controlling feral hogs as described in the draft label for the product "Kaput® Feral Hog Bait". However, if a future registration of this use is sought, additional toxicology, residue chemistry and occupational data may be required.

Detail Consideration

The study will be conducted in the state of Texas in a fenced area, no bigger than 2,471 acres (10 km^2). The amount of formulated product is not to exceed 12,600 lbs. As part of the EUP study, all the test animals that consume the test product will be sampled to determine the residue levels. Based on previous work, the company claims that 100% efficacy is expected when feral hogs are fed on the bait containing 0.005% warfarin for 5 days and the low concentration of warfarin along with the requirement of multiple dosings will also reduce risk to non-target animals. The formulated product contains a blue dye to cause staining of the tissues of the test animals and prevent their consumption. In addition, the bait stations will be continuously monitored by cameras, assuring non-target animals not gaining access to the bait.

Use Directions: The use pattern summary is taken from the Kaput® Feral Hog Bait label that is in the EUP application. The Kaput® Feral Hog Bait product will be used to control only feral hogs on rangeland, forests, non-crop areas, and crop lands. The product is formulated as a granule that will be added to each HOGHOPPER feeder or similar feeder with a heavy lid that prevents non-target animals from accessing the bait. The label specifies that the bait not to be applied on the ground. It also specifies to "apply bait in fenced areas and avoid application in open range areas". The Kaput Feral Hog Bait label clearly directs handlers to "wear protective gloves when handling bait or animal carcasses". Twenty-five to one hundred pounds of the bait will be placed into each feeder. The animal access door will be closed limiting access to feral hogs only. Treatment should continue for ten to twenty-one days. The feeder will be monitored and refilled as needed, approximately every two to five days, depending on the number of feral hogs that visit the feeder. The label instructs the applicators to "return to the treatment site within 4 days of application and at a 2-5 day intervals thereafter to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface."

Hazard Identification/Toxicology: No acceptable Guideline toxicity studies on warfarin are available except for acute toxicity submissions. The Agency has based its determinations relative to human safety on human evidence and experience. If a future registration of this use is sought, based upon designation as a food or non-food use,

additional data may be required to fulfill the revised 2007 40 CFR Part 158 Toxicology Data Requirements.

Warfarin, a synthetic analogue of vitamin K, is a member of the coumarin family of blood anticoagulants. The sodium salt of warfarin is used as an anticoagulant in the treatment of individuals with hyper-coagulation problems. Its toxicity, mechanism of action, and treatment of overdose in humans are well established.

Warfarin toxicity is manifested in an increase in prothrombin and partial thromboplastin times and a decrease in the vitamin K dependent clotting factors, II, VII, IX and X. Bleeding time, clot retraction, platelet counts, thrombin time, and euglobulin lysis times are usually normal. Signs of toxicity include cutaneous bleeding, hematuria, melena or hematochezia, hematomas, uterine bleeding in women, epistaxis and gingival bleeding. Death follows excessive external and/or internal bleeding.

Technical grade warfarin has high acute toxicity *via* oral or inhalation (dust aerosol) routes of exposure (Toxicity Category I) and low acute toxicity *via* dermal route (Toxicity Category III). It is not an eye or skin irritant. There was no skin hypersensitive study available; however, human data indicates that warfarin does not induce allergic reaction. Warfarin has clearly been established as a human teratogen at clinical doses. Birth defects have been observed as a result of exposure to coumarin anticoagulants during any trimester of pregnancy.

Residue Chemistry: No residue chemistry data required for the purpose of this limited EUP use of warfarin. However, based on the use profile for warfarin in/on rangeland, forests, non-crop areas, and crop lands where livestock exposure cannot be monitored or prevented, if a future registration of this use is sought, data on livestock, as set forth in OPPTS residue chemistry test guidelines 860 series may be required.

Dietary Exposure: Negligible dietary exposure is expected as a result of this EUP use. Possible routes of dietary exposures would be through feral hogs or livestock which may feed on the bait. However, the chance of affected feral hogs or livestock being consumed as food are minimal due to the requirement of multiple dosages, staining of tissues of animals which fed on the bait, placement of monitoring cameras in each station, and retrieving of animal carcasses. Exposure through drinking water is also expected to be negligible, if any, for this EUP use since warfarin baits are used off the ground and in limited quantities. If a future registration of this use is sought, data may be required as described under residue chemistry section above and HED will reevaluate dietary exposure.

Occupational Exposure: There is no mixing or loading in the typical sense of most pesticide applications although there is the potential for exposure to occupational handlers who are placing the bait into the feeder. In order to curtail the potential inhalation exposure to workers loading granules HED recommends the use of a respirator. However, no toxicological points of departure have been established for warfarin. HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a

pesticide. In the case of warfarin, there is a minimal potential for post-application dermal exposure to workers since the label clearly states "wear protective gloves when handling bait or animal carcasses". A quantitative occupational handler and post-application exposure assessment does not need to be completed to conclude with reasonable certainty that occupational exposures to Kaput® Feral Hog Bait do not pose a significant human health risk.

Jacobs, William

From: Jacobs, William
Sent: Monday, November 25, 2013 11:53 AM
To: Sahafeyan, Mohsen
Subject: RE: warfarin

Great. Thank you. Please let me know when it is ready.

From: Sahafeyan, Mohsen
Sent: Monday, November 25, 2013 11:13 AM
To: Jacobs, William
Subject: RE: warfarin

Thank you for response. We did not discuss food/non-food per se, rather we did a qualitative risk assessment; the branch is reviewing it now and it may be ready by Wednesday.

From: Jacobs, William
Sent: Monday, November 25, 2013 7:50 AM
To: Sahafeyan, Mohsen
Subject: RE: warfarin

There is no petition number. At this time, the product is proposed only as an experimental non-food use (affecting free-ranging, feral hogs rather than swine raised as livestock). The dye in the bait is intended to turn fat blue, thus making the hogs unattractive as a food source for hunters. Your assessment should discuss the food-use/non-food-use issue.

From: Sahafeyan, Mohsen
Sent: Tuesday, November 19, 2013 10:09 AM
To: Jacobs, William
Subject: warfarin

Hi Bill,
Do you have petition number for EUP action of warfarin? I have DP# D413046 and Registration Nos.: 72500-EUP-E, not petition number. Thanks.

Mohsen Sahafeyan
EPA/OPP/HED/RAB6
703-305-0776 (voice)
703-305-0871 (fax)

Jacobs, William

From: Jacobs, William
Sent: Wednesday, October 30, 2013 7:52 AM
To: Baris, Reuben
Subject: RE: Feral Hogs and Section 18

Except for today's pizza thing and tomorrow's staff meeting, I am free both days from ~7:30 AM to 4 PM. Elizabeth Riley of EFED gave me some preliminary comments on the EUP application. Someone in HED (I'll have to see if I can find the name) contacted me in September about this but I have not seen a completed review from EFED or HED yet. Elizabeth might want to participate in the call . Both Elizabeth and I would like to see a better experiment (and better documentation of it) than what Scimetrics has proposed. I'm not sure that the next step would be product registration no matter what the results of the proposed research might be.

A notice of receipt for the EUP application has been published and is in its comment period.

For a Section 18, the application would have to describe an emergency. (Sometimes, "emergencies" are more political than biological.) OPP could impose conditions on the exemption, if granted, that might aid in the garnering of useful information. The proposed time for the EUP research is next summer. Interventions under an emergency exemption could begin as soon as it was granted (or sooner if the State declared a crisis). Someone from the Branch that handles Section 18's should be on the call if there is to be discussion of going that route.

From: Baris, Reuben
Sent: Tuesday, October 29, 2013 6:16 PM
To: Jacobs, William
Subject: FW: Feral Hogs and Section 18

Hi Bill,
Are you available either day? What times work for your schedule?
reuben

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Tuesday, October 29, 2013 6:06 PM
To: Baris, Reuben
Cc: richard@genesislabs.com
Subject: Fwd: Feral Hogs and Section 18

Reuben:
Our company has been working with Texas Department of AG for the past years concerning Feral Hogs. We recently had a question regarding a Section 18 emergency exemption, and would like to get your input. Richard Poche, the owner of Scimetrics, and I would like to give you a call. Would Wednesday, Oct. 30th, or Thursday, Oct. 31st, work for you? If so, what time will be convenient for you? Please let us know. We are looking forward to working with you! With best regards, Sue.

---------- Forwarded message ----------
From: **Hebert, John** <Hebert.John@epa.gov>
Date: Tue, Oct 29, 2013 at 3:11 PM

Subject: RE: Feral Hogs and Section 18
To: Sue Valentine <sue@scimetricsltd.com>
Cc: "richard@genesislabs.com" <richard@genesislabs.com>, "Baris, Reuben" <Baris.Reuben@epa.gov>

Hi Sue – I'm no longer working in RD; I'm staying in the Antimicrobials Division permanently. So, Reuben Baris should be your direct contact for all your rodenticide/vertebrate pest issues. It's been good to work with you over the past few years and hopefully we'll have the chance to do so again. Feel free to contact me if you ever need anything.

Take Care,

John

****

John Hebert, Acting Branch Chief

Regulatory Management Branch I

Office of Pesticide Programs

Environmental Protection Agency

703-308-6249

From: sue@kaputproducts.com [mailto:sue@kaputproducts.com] **On Behalf Of** Sue Valentine
Sent: Tuesday, October 29, 2013 5:02 PM
To: Hebert, John
Cc: richard@genesislabs.com
Subject: Fwd: Feral Hogs and Section 18

Hi John:

We still would like your input regarding a Section 18 for TX and Feral Hogs. See my email below. Richard and I would like to give you a call on Wednesday or Thursday. What day and time would work for you? Let me know. Thank you! Sue.

---------- Forwarded message ----------
From: **Sue Valentine** <sue@scimetricsltd.com>
Date: Thu, Oct 3, 2013 at 11:02 AM
Subject: Feral Hogs and Section 18
To: "Hebert, John" <Hebert.John@epa.gov>
Cc: richard@genesislabs.com

Hi John:

I have a question for you regarding Pesticide Emergency Exemptions. Texas Dept. of Ag has been talking to us regarding Feral Hogs. As you may know, the feral hog population is increasing by the minute, and so are the economic and ecological losses. TDA is considering asking for a Section 18. Dale Scott knows that we have submitted an EUP for Feral Hogs to EPA, and that we have done a feral hog study in TX in 2008. That study is referenced in our EUP. Would data submitted in that study be enough to obtain an Emergency Exemption?

Here is what Dale emailed to Richard:

"Richard,
TDA would be willing to submit the Section 18 if we have adequate data, etc, if EPA gives us the indication that it would receive approval. However, TDA cannot be the requester on any Secton 18. I hope that helps.

Dale"

I am a little confused why Dale says TDA cannot be the requester on any Section 18. Anyways, if you could give me some input regarding Section 18 pertaining to Feral Hogs, I would appreciate it.

In your opinion, how likely is it that EPA would grant TDA an Emergency Exemption at this point?

Thanks for your help. Best regards, Sue.

Sue Valentine

Scimetrics Ltd. Corp.

PO Box 1045

Wellington, CO 80549

Ph. 970-482-1330

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Ph. 970-482-1330

IRB EFFICACY REVIEW

PRODUCT NAME:	KAPUT® FERAL HOG BAIT
PRODUCT FILE SYMBOL:	72500-EUP-E
REGISTRANT:	Scimetrics Ltd. Corp. Wellington, CO 80549
DATE COMPLETED:	10/23/2013
DP NUMBER:	414617
DECISION NUMBER:	479666
DATES OF SUBMISSION:	6/7/13 (received 6/10/13), 8/1/13 (received 8/1/13) both sent for review 8/15/13)
ACTIVE INGREDIENT:	Warfarin
FORMULATION:	0.005% Warfarin bait blocks
TYPE OF PRODUCT:	Rodenticide
PURPOSE:	Experimental field use of product in Texas
DATA MRID NUMBERS:	None
GLP CLAIMED:	No
TEAM REVIEWER:	William W. Jacobs, Ph. D.
EFFICACY REVIEWER:	William W. Jacobs, Ph. D.
SECONDARY REVIEWER:	Gene Benbow

10-28-13

BACKGROUND

This product is a 0.005% Warfarin bait block proposed for experimental use under §5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended

> ... to control only feral hogs (*Sus scrofas* [sic]) on rangeland, forests, non-crop areas and crop lands.

The text quoted above appears in the first sentence of the "**USE RESTRICTIONS:**" subsection of the "**DIRECTIONS FOR USE**" section on the proposed experimental use permit (EUP) label.

Scimetrics Ltd. submitted the application for this EUP on 6/7/13. The submitted items considered in this efficacy review include are enumerated below.

1. A letter dated "June 7, 2013" from Sue Valentine, Scimetrics' "Regulatory Manager"
2. A completed registration application form dated "06/07/2013" signed by Valentine
3. A completed Confidential Statement of Formulation (CSF) form dated "**June 7, 2013**" and attributed to and signed by Valentine

4. A copy of a 3-page label proposed for "**Kaput® Feral Hog Bait**" and marked "EUP Application June 7, 2013

5. A document entitled "**EXPERIMENTAL USE PERMIT APPLICATION**" and dated "June 7, 2013

6. An efficacy report (fully cited below) entitled "Development of a Novel Feral Hog (*Sus scrofa*) Bait", which was submitted on 8/1/13

Scimetrics has been interested in developing this type of product for several years. On 4/14/11, OPP personnel met with company representatives to discuss data requirements for such a registration.

There have been feral hogs in lands that are now included in the USA since the DeSoto expeditions in the 1500's, with subsequent deliberate and inadvertent introductions. There now are significant populations of feral hogs in many States, where the animals are linked to crop damage, other property damage, predation on young wildlife and livestock, and the spread of some diseases. The efficacy report discussed below lists many of the problems related to feral hogs that have been reported in the US and elsewhere.

For many mammalian species, Warfarin is one of the more forgiving of the anticoagulant rodenticides. Warfarin is very toxic to swine, however. Timm (1994), who summarized then-available toxicity data for anticoagulant rodenticides, cited an acute oral LD_{50} figure of 3 mg Warfarin per kg of body weight for swine and a 7-day subchronic LD_{50} value of 0.05 mg Warfarin per kg of body weight.

DATA SUMMARY

Formulation

The CSF dated "**June 7, 2013**" is discussed in a confidential attachment at the end of this review.

Efficacy Data

The EUP application document alludes to an efficacy report that was not submitted with the application. At my request, Valentine submitted the report that is cited and discussed immediately below.

Davis, N.E. (2008) Development of a novel feral hog (*Sus scrofa*) bait. Unpublished report, Study No. N08019, Genesis Laboratories, Inc., Wellington, CO, 58 pp.

MRID# 479502-03

Davis (2009) reports on several trials in which captive domestic pigs and feral hogs were tested for responses to placebo and toxic baits of various formulations. Trials were run in Colorado and at the USDA National Wildlife Research Center's (NWRC) field station in Kingsville, TX. Personnel from Genesis Laboratories and the NWRC participated in the conduct of the study. Raw data sheets were not appended to the report as submitted.

The first phase ("**OBJECTIVE I**") of the reported research involved testing 10 recently captured feral hogs for responses to two rodenticide-free bait formulations that were "formulated at Genesis Labs" and "extruded at Scimetrics" prior to being shipped to the Kingsville facility for bioassays. The hogs were penned together for ~2 weeks before the trial began. For testing, hogs were kept individually in 10'-X-12' pens, fed 0.907 kg (~2 lbs) of USDA Pig 3800 diet, and offered water "*ad libitum*" for a 1-day "acclimation period".

For the test period, the maintenance ration (apparently) was removed, and the animals were presented with a choice between the Genesis/Scimetrics diet with a strawberry flavor added and the same material without the strawberry flavor. The strawberry flavor was selected because study personnel had encountered a report suggesting that some types of nontarget organisms would be averse to it.

Results of this dietary choice test are summarized in the table shown immediately below. Except for one animal (68 Red) that ate little of either diet, the hogs strongly preferred the preparation that lacked the strawberry flavor. Nevertheless, baits with the strawberry flavor were used in subsequent trials "do [sic] to other research showing that strawberry flavoring will possibly detour [sic] other animals." One of the baits used in this trial reportedly tested positive for a trace of Warfarin. Davis does not seem to indicate which diet (with or without strawberry flavor) tested positive.

Subject Number	Consumption (kg)		Acceptance of Strawberry Flavor
	G/S Bait w.o. Strawberry	G/S bait with Strawberry	
19	2.005	0.415	17.1%
22	4.410	0.560	11.3%
23	1.740	0.150	7.9%
55	2.620	0.000	0.0%
67	2.730	0.860	24.0%
68	2.720	0.035	1.3%
68 Red	0.030	0.035	53.8%
72	4.350	2.160	33.2%
74	3.770	0.860	18.6%
75	0.115	0.040	25.8%
Totals	24.49	5.115	17.3%
Means	2.449	0.512	21.0%

Note: "Acceptance of Strawberry Flavor" is refers to the percent of total calculated consumption of both diets that was comprised by the one with strawberry flavor added to it.

Davis notes that "Diarrhea and vomiting was [sic] seen in several hogs." Some hogs reportedly did not eat (very much?)

> ... while in the acclimation phase or on trial, but resumed eating once released into the post test holding pens.

The second phase of the laboratory trials with captive animals ("**OBJECTIVE II**") involved 52 feral hogs. In "Test I" of this phase, 4 test groups of 4 hogs each were created. One group was fed a nominally 0.0125% Warfarin bait for 3 consecutive days, and another group was fed that bait for 5 consecutive days. A third group was fed a nominally 0.001% Diphacinone bait for 3 consecutive days, while the fourth group received that bait for 5 consecutive days. These hogs were "fasted over night" prior to presentation of bait. The amount of bait presented per animal was "approximately 2.28 kg" (~ 5 lbs). Bait weigh-backs were conducted during morning hours. Water was supplied "*ad libitum*". Following "Test I", and also "Test II" and "Test III" (discussed below), surviving subjects "were moved to a post test pen and observed for approximately 14 days." These newly group-caged animals were offered "approximately 12 kg of the alternative diet and water was available *ad libitum*."

The next table summarizes bait reported consumption data for the Warfarin portion of Test I. All subjects in both test groups took more than 2.5 kg (>5.5 lbs) of treated bait. Three of 4 hogs in the 0.0125%-Warfarin-3-days group died in 6-8 days. All 4 hogs offered that bait for 5 days died in 6-9 days.

Animal ID No.	Sex	Daily Bait Consumption (kg)					Total (kg) Eaten
		1	2	3	4	5	
0.0125% Warfarin Bait for 3 Days							
52	M	1.140	0.860	0.885	-	-	2.885
61	M	1.015	0.615	1.085	-	-	2.715
65	F	1.005	1.750	1.675	-	-	4.430
74	F	2.150	1.510	2.230	-	-	5.890
0.0125% Warfarin Bait for 5 Days							
NT	M	2.180	1.995	2.130	2.250	2.110	10.665
53	M	0.825	0.420	0.580	0.500	0.245	2.570
24	F	1.735	1.830	1.915	2.260	2.255	9.995
56	F	1.905	1.675	1.630	0.025	0.015	5.250

The next table summarizes consumption data for the Diphacinone portion of Test II. As with the groups fed 0.0125% Warfarin, all hogs reportedly ate more than 2.5 kg of treated bait. However, 7 of 8 hogs in the 0.001% Diphacinone groups survived, with the only death being in the group fed that bait for 3 days. Male hog #71 died 5 days after the onset of Diphacinone exposure.

Animal ID No.	Sex	Daily Bait Consumption (kg)					Total (kg) Eaten
		1	2	3	4	5	
0.001% Diphacinone Bait for 3 Days							
26	M	0.680	0.910	0.945	-	-	2.535
71	M	1.325	0.975	1.575	-	-	3.875
56 G	F	0.875	0.980	1.195	-	-	3.050
57	F	1.370	1.595	1.445	-	-	4.410
0.001% Diphacinone Bait for 5 Days							
18	M	0.665	1.150	0.795	0.745	0.930	4.285
27	F	1.070	0.865	0.935	1.215	1.565	5.650
55	F	1.570	0.885	0.945	1.575	1.640	6.615
58	F	0.970	0.955	1.200	1.160	1.265	5.500

Symptoms of toxicosis were found, collectively, among subjects in all 4 "Test I" groups. Relative to the Diphacinone groups, a greater total of number of different symptoms and the only reported external hemorrhaging were seen in the Warfarin-fed groups. It is clear, however, that Diphacinone can kill feral hogs. For example, hog deaths were reported as nontarget effects in a 2003 aerial-drop-and-bait-station application on the island of Hawaii. The nominal Diphacinone concentration in the product(s) involved in that case was 0.005%, which is the concentration used in Diphacinone baits registered in the U.S. to control commensal rodents. Perhaps use of a higher concentration than 0.001% would have produced more Diphacinone-related mortalities in hogs than were observed in the Davis (2008) trials.

"Test II" of "**OBJECTIVE II**" included 2 test groups of 4 hogs each. One group was fed a nominally 0.025% Warfarin[1] bait for 1 day, and another group was fed that bait for 2 consecutive days. The amount of bait initially provided was "Approximately 3.195 kg" (~7 lbs), evidently with replenishments in at least some cases. Water was supplied "*ad libitum*". Bait weigh-backs were conducted during morning hours.

Bait consumption data for "Test II" are summarized in the next table. Considering the higher Warfarin concentration and the shorter exposure durations as compared to the Warfarin portion of "Test I', bait consumption by "Test II" hogs was substantial. All animals in the 1-day group took 1.360 kg of bait; and all hogs in the 2-day group took more than twice that much. The 2-day

[1] Most of the Warfarin baits ever registered to control commensal rodents in the U.S. had the nominal concentration of 0.025% Warfarin.

exposure period was sufficient to kill all 4 subjects (in 5-11 days), but 2 of 4 hogs in the 1-day group survived despite the amounts of bait consumed by them on that one day. The victims in the group with one day of exposure died 8 and 11 days after the Warfarin bait first was offered.

Animal ID No.	Sex	Daily Bait Consumption (kg)					Total (kg) Eaten
		1	2	3	4	5	
0.025% Warfarin Bait for 1 Day							
NT Male	M	2.165	-	-	-	-	2.165
No Ear	F	1.360	-	-	-	-	1.360
21	F	2.410	-	-	-	-	2.410
58	F	2.350	-	-	-	-	2.350
0.025% Warfarin Bait for 2 Days							
NT Female	F	1.175	1.565	-	-	-	2.740
63	F	3.200	2.740	-	-	-	5.940
67	F	2.580	1.870	-	-	-	4.450
72	F	1.615	1.590	-	-	-	3.205

"Test III" of "**OBJECTIVE II**" included 2 test groups of 4 hogs each. One group was fed a nominally 0.005% Warfarin bait for 3 consecutive days, and another group was fed that bait for 5 consecutive days. The amount of bait initially provided was "approximately 3.200 kg" (~7 lbs). Water was supplied "*ad libitum*". Bait weigh-backs were conducted during morning hours.

Bait consumption data for "Test III" results are summarized in the next table. Despite the presence of the nominally 0.005% Warfarin bait for at least 3 days, two hogs had cumulative consumptions of less than 2 kg of it. All 4 hogs fed the 0.005% Warfarin bait for 5 days died during the trial (after 7-8 days), but only 1 of 4 animals offered that bait for 3 days expired (Male 61, 4 days after the onset of exposure). All subjects in the 5-day group had calculated consumption of bait on at least 4 days, but some of the amounts reported were very small, considering the size range for feral hogs. Hemorrhaging was seen in hogs in both groups.

Animal ID No.	Sex	Daily Bait Consumption (kg)					Total (kg) Eaten
		1	2	3	4	5	
0.005% Warfarin Bait for 3 Days							
30	M	2.980	1.710	1.930	-	-	6.620
61	M	1.425	0.170	0.005	-	-	1.600
54	F	1.485	1.445	1.570	-	-	4.500
60	F	2.180	0.610	1.520	-	-	4.310
0.005% Warfarin Bait for 5 Days							
59G	M	2.350	1.995	1.840	2.060	2.120	10.365
59R	M	1.280	0.610	1.520	1.750	1.820	6.980
6bai9	F	1.575	0.765	1.035	0.015	0	3.390
75	F	1.295	0.020	0.005	0.175	0.035	1.530

As with other species, Warfarin-related mortalities occurred several days to more than a week after the onset of exposure. The occurrence of repeated exposures was more important than the amount of any one exposure event, with the time to death being relatively independent of the level of dosage, as long as the level of exposure was sufficient to be lethal.

Reported results of chemical analyses of the baits used in the "**OBJECTIVE II**" trials are summarized below.

Test #	Active Ingredient	Nominal Concentration	Assayed Concentration
I	Warfarin	125 ppm	130.3 ± 2.4 ppm
	Diphacinone	10 ppm	10.2 ± 0.2 ppm
II	Warfarin	250 ppm	273.7 ± 3.6 ppm
III	Warfarin	50 ppm	71.2 ± 2.7 ppm

Considering that the bait used in "Test III" assayed at >40% over-formulation and seemed to require at least some feeding for more than 3 consecutive days, the inference that 0.005% Warfarin is the right concentration for field trials seems to have been an inductive leap rather than a considered deduction. It might be a good idea to run additional pen trials comparing 0.005% and 0.010% Warfarin baits (without peppermint flavor) before starting field trials or to greatly expand the intended field trials to allow those concentrations to be compared under conditions mimicking operational use. The 0.01% Warfarin concentration is almost exactly midway between the assayed concentrations of the nominally 0.005% and 0.0125% baits which provided somewhat similar results in limited trials with captive animals (i.e., 4 of 4 killed with 5 days of feeding and <4 of 4 killed with 3 days of feeding).

"**OB JECTIVE III**" of the research reported by Davis (2008) involved recorded observations of activities at bait dispensers. DECONYX® trail cameras were used for this purpose and were set up to capture activity at 2 dispensers which were situated in a pasture at the Kingsville research station. Apparently, no feral hogs were in the pasture.

Initially, the dispensers were baited, left open, and checked daily. One of the dispensers was emptied or nearly emptied for 3 straight nights, after which it was loaded but kept closed for 2 additional nights. The other baiter received little attention for 3 nights, then was emptied by animals on the fourth night, and finally was left closed and monitored for one night.

One of the dispensers received greater attention than the other and was emptied on the fifth and last night of the trial despite having been left closed. The only animals detected as successfully raiding closed dispensers were collared peccaries (*Dicotyles tajacu*), which are pig-like mammals native to parts of North and South America. In addition to peccaries, Norway rats (*Rattus norvegicus*), raccoons (*Procyon lotor*), and coatis (*Nasua nasua*) fed from open dispensers. Except for the peccaries, closed dispensers reportedly frustrated those animals plus white-tailed deer (*Odocoileus virginianus*), woodrats (*Neotoma* spp.), and opossums (*Didelphis virginiana*).

Proposed Experimental Program

The research for which this EUP application was filed would be performed in one or more fenced pastures located in at least one of the following counties situated in or near to the Texas panhandle region: Briscoe, Hall, Jones, or Motley. Descriptions of the program suggest that a single site is to be used with the total test area "Not to exceed 10 km^2 or 2,471 acres."

Bait is to be applied "in feeders with active feral hog sign" with feeders being "spaced to limit duplicate hog visitation." Bait application would occur "from spring to summer and not overlapping big game hunting seasons." Bait dispensers would be loaded with 25-100 lbs of a 0.005% Warfarin bait and would be "refilled as needed for the duration of the 3 week experimental phase."

Scimetrics states in one place that the "total amount of bait applied will not exceed 10,000lbs [sic]" but, in several other places, projects that 12,600 lbs. of finished bait would be needed for the study. The latter amount of bait formulated at 0.005% a.i. would contain 0.63 lbs. of Warfarin. Scimetrics also projects that the amount of bait requested would be sufficient to supply 6 lbs of

feed/day to 100 hogs for 21 days (apparently assuming no toxic effects or consequent loss of life or ability to feed). The amount of bait potentially proffered would be equivalent to 600 lbs/day. At 25-100 lbs. bait/dispenser/day, such a baiting rate would entail use of 6-24 dispensers. At minimum, these dispensers would be deployed in a single pasture located in one of the four counties mentioned above. As the outline of the experimental program mentions "final field locations yet to be determined" and also a "treatment area" and a "Study site", it is not clear whether more than one treated area would be included in the final experimental design.

Effects of treatment would be measured via use of "a passive tracking index" (the cited reference for which – Engeman, *et al*, 2001 -- does not appear in the bibliography for the permit application).[2] Initial assessments using this procedure and possibly others would begin "approximately 3 weeks" before toxic bait application.[3] The 21-day baiting period is to be followed by "a 3 week post-exposure census." It is not immediately clear how the procedures employed by Engeman, *et al* (2001), who cleared tracking patches on sandy primitive roads to obtain counts of hog tracks, would be adapted to the proposed field trial that is to be conducted in one or more pastures. Under the circumstances in which those researchers employed it, the passive tracking index seems to have worked well.[4] Engeman, *et al* (2013), recently have reviewed several methods that have been used around the world to monitor populations and activity of feral swine.

There is no mention of doing similar concurrent monitoring in a similar pasture located far enough away from the baited one so that hogs in the check area would be affected by seasonal factors but not by the Warfarin bait.[5] There also is no mention of using radio telemetry to learn the fates of specific animals, although hog carcasses might be found opportunistically.

Scimetrics also proposes to document which species are able to access bait from HOGHOPPER™ bait dispensers. Bait dispensers are to be "continuously monitored by motion activated camera". Such cameras should be able to detect activity near the dispensers, including successful and unsuccessful attempts to access bait as well as events of bait spillage. However, it is not made clear that one motion-detection camera would be available for each of the 6-24 bait dispensers that the proposed research appears to require.

The outline of the experimental program discusses monitoring stations for bait spillage and removing spillage ("to prevent nontarget access") but does not describe procedures that might be employed to quantify the extent of bait spillage that occurs around the dispensers.

That which could be expected to be learned from the proposed trial about the efficacy of the test material would be limited to whether application of the bait in dispensers was associated with reduced hog traffic in the treated pasture(s), the species that were and were not able to access bait directly from the dispensers where cameras were in place, and the occurrence but not the amount of spillage from HOGHOPPER™ bait dispensers.

The outline of the experimental program states that

> The bait is specifically designed for optimal palatability for feral hogs and as such it is likely that many non-target animals will not find it palatable.

---

[2] On 9/17/13, I obtained from its first-listed author a copy of the report cited for the passive tracking index. He (Richard Engeman) also supplied several other relevant papers.

[3] According to the experimental program, along with the "passive tracking index", "Additional census methods may be employed as needed depending or [sic] terrain and population densities."

[4] The tracking index is called "passive" because no the tracking patch has no stimulus for attracting swine deliberately added to it.

[5] The implied assumption seems to be that hog traffic would not decline in the absence of Warfarin use. Other factors (e.g., out-of-season hunting, disease, abrupt change in weather, etc.) also might affect the amount of hog traffic in the study area.

The EUP application package presents no data which support these assertions. The proposed test material does not appear to be identical to any of the baits tested by Davis (2008) and, apart from the active ingredient and the blue dye, contains no candidate substance for deterring nontarget species. That rodents -- nontarget species in this case -- and other types of animals will eat wax bait blocks has been established through decades of efficacy research and reports of nontarget incidents. See CONFIDENTIAL ATTACHMENT for more detailed discussion of bait composition.

Label

The label for a product being used under an experimental label must include required label elements and restrictions appropriate for the chemical and formulation under study but also should be written such that it does not prohibit the proposed research from being conducted as outlined in the experimental program. The experiment(s) to be conducted under the permit provide a proving ground for the use(s) under study. If the trials are successful, the procedures used in them should later be reflected on the label of a registered product, provided that registration for the use is sought and that the procedures followed are consistent with practices that EPA allows for the active ingredient.

The proposed label for 72500-EUP-E would allow use of the hog bait "on rangeland, forests, non-crop areas, and crop lands" but not in specifically in fenced pastures, which apparently is the type of site where the proposed research would be conducted. If still being used for raising livestock, fence pastures could be construed as falling within the category "crop lands", although simultaneous use of lands for grazing livestock and controlling feral hogs should not be permitted or occur. Despite listing "rangeland" as a permitted use site, the label's "**USE RESTRICTIONS:**" subsection of the "**DIRECTIONS FOR USE**" states "avoid application in open range areas." Bait is to be applied "in fenced areas", which essentially means pastures, some of which in Texas are extremely large.

The proposed "**USE RESTRICTIONS:**" also direct that users "not apply this bait on the ground" and "Use a HOGHOPPER™ feeder or similar feeder with a heavy lid" so as to keep "non-target animals from accessing the bait". The "**BAIT APPLICATION:**" subsection includes the command "**Leave no bait on soil or outside the feeder.**" Users are directed to monitor and refill feeders "as needed, approximately every 2-5 days" -- a schedule that would make compliance with the "**Leave no bait**" command rather challenging if there were spillage. Elsewhere (in the "**SURVEILLANCE AND FOLLOW UP:**" subsection), the label states that users

> ... must return to the treatment site within 4 days of application, and at 2-5 day intervals thereafter, to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface.

If not impractical due to frozen ground, hog carcasses are to be buried "on site in holes dug at least 18 inches deep." Due to the large size of many feral hogs, a hole dug only 18 inches deep would not allow some carcasses to be completely covered by soil unless a mound were constructed over the body. At minimum, the direction should be that holes for burying carcasses must be deep enough so that the body can be covered by at least 18 inches of soil. Burials at such depth would not necessarily keep all scavengers potentially at risk from Warfarin from finding and consuming hog carcasses.

The label advises that "Treatment should continue for 10-21 days". Such duration would cover the 21-day bait application period outlined in the experimental program.

CONCLUSIONS

It is not clear that prior research has established that 0.005% is the appropriate concentration of Warfarin to use in a bait product of this type. The inference of "100% efficacy" drawn from research reported by Davis (2008) is based on the fates of 4 hogs that were exposed for up to 5 days to a bait that was shown by chemical assay to have been 0.00712% (±0.00027%).

Much more could be learned from the proposed research plan if the changes listed below were incorporated.

1. Increasing the number of test plots

2. Adding one or more untreated plots which would be monitored but not treated with toxic bait (placebo bait?)

3. Assessing a higher Warfarin concentration (e.g., 0.01%) as well as 0.005% in the same bait matrix

4. Outlining the procedures that would be followed for the passive tracking index, including how it would be adapted for use in fenced pasture areas

5. Incorporating into the research design a second census method for assessing the effects of treatment

6. Using radio telemetry to document the fates of some hogs exposed in the test situation and to aid in rapidly locating "fresh" victims for necropsy and tissue collection for carcass residue determinations

7. Checking bait dispensers daily (early morning, if possible) to quantify residual amounts of bait spillage around dispensers.

As the proposed research would be conducted in what amount to fenced-pasture areas, the proposed experimental use permit (EUP) label must be revised to include fenced pastures as a permitted use site. Use in unfenced rangeland is prohibited by the proposed EUP label. Consequently, "rangeland" should not be permitted as a use site. Other changes needed for the EUP label are enumerated below. Additional label modifications are likely to be needed if this use pattern is proposed in an application for registration under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

1. Replace the third bulleted item in the "**USE RESTRICTIONS:**" subsection of "**DIRECTIONS FOR USE**" section with the text shown below.

   > Apply bait only in fenced areas. Do not use this product in unfenced, open rangelands.

2. Replace the third sentence of the "**BAIT APPLICATION:**" subsection of the "**DIRECTIONS FOR USE**" with the text shown below.

   > Continue treatment for 10-21 days. Monitor feeders every 1-5 days. Refill feeders if bait is significantly depleted or degraded and there still is evidence of hog activity at the feeder.

3. In the fifth and sixth sentences of the "**BAIT APPLICATION:**" subsection, change "may have" to "has".

4. Change the subheading "**SURVEILLANCE AND FOLLOW UP:**" to "**SURVEILLANCE AND FOLLOW-UP:**" (i.e., insert a hyphen). In the second sentence of this paragraph, change "2-5 day" to "2- to 5-day". Replace the fourth sentence of this paragraph with the text shown below. Note that a hole dug 18 inches deep would not put the entire carcass of some feral hogs underground.

   > Bury carcasses on site in holes dug deeply enough that the entire carcass is at least 18 inches below ground level. Cover carcasses with earth up to the level of the surrounding ground.

5. The commas in the last sentence of the "**SURVEILLANCE AND FOLLOW-UP:**" paragraph are not needed and should be deleted.

REFERENCES

Engeman, R.M., Constantin, B., Nelson, M., Woolard, J. and Bourassa, J. (2001) Monitoring changes in feral swine abundance and spatial distribution. Foundation for Environmental Conservation, 28:3, 235-240.

Engeman, R.M., Massei, G., Sage, M., and Gentle, M.N. (2013) Monitoring wild pig populations; a review of methods. Environmental Science and Pollution Research, Springer-Verlag, Heidelberg, Germany, DOI 10.1007/s11356-013-2002-5, 15 pp.

Timm, R.M (1994) Description of active ingredients. In: Prevention and Control of Wildlife Damage (S.E. Hyngstrom, R.M. Timm, and G.E. Larson, eds.), University of Nebraska Cooperative Extension, U.S. Department of Agriculture, Great Plains Agricultural Council Wildlife Committee, G-23 to G-61.

F I F R A

CONFIDENTIAL BUSINESS INFORMATION
DOSE NOT CONTAIN
NATIONAL SECURITY INFORMATION (EO 12356)

Some information in the attached material may be entitled to treatment as trade secret or proprietary data section 7(d) and section 10 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended.

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure while in his/her own advantage or to reveal any confidential information (except to person needing the information for the performance of official duties). A penalty of up to $10.000 fine and up 3 years imprisonment may result from conviction of a violation on section 12(a)(2)(D).

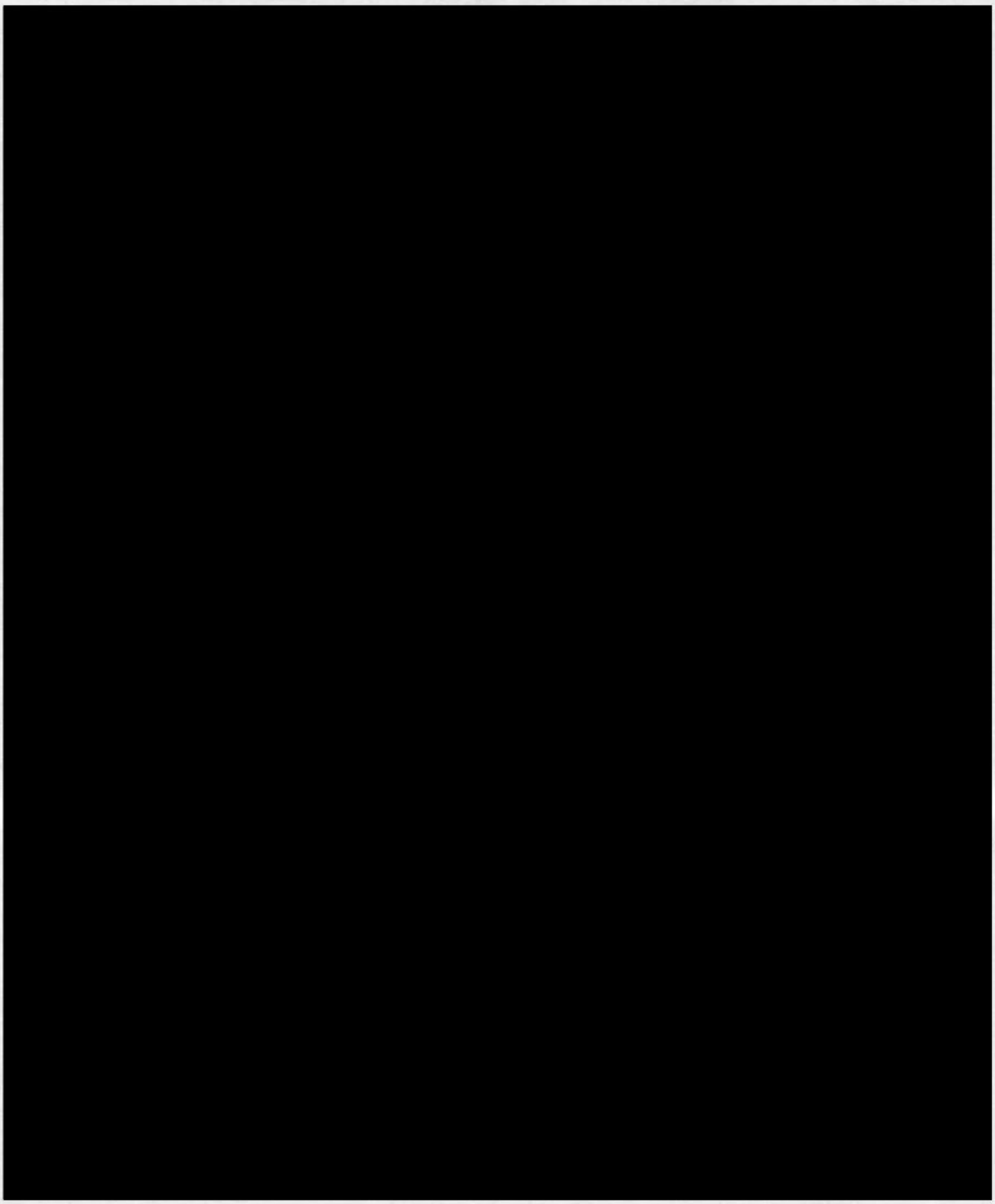
Section 10(f) makes it a crime for any employee to disclose confidential information except as authorized by section 7 and 10 of FIFRA. A penalty of up to $10.000 fine and up to one year in jail may result from conviction of a violation of section 10(f).

The attached information is not to be published, reproduced, publicly discussed, included in response to an FOI request or otherwise released without the explicit written authorization of the appropriated division or his designee.

Inert ingredient information may be entitled to confidential treatment

[redacted]

Inert ingredient information may be entitled to confidential treatment



Jacobs, William

From: Jacobs, William
Sent: Tuesday, September 03, 2013 2:53 PM
To: Riley, Elizabeth
Subject: RE: Feral Hog EUP Comments

Internal and Deliberative – Do Not Release

[redacted]

From: Riley, Elizabeth
Sent: Tuesday, September 03, 2013 1:23 PM
To: Jacobs, William
Subject: Feral Hog EUP Comments

Hi Bill,

I just realized that I forgot to send you the comments on the EUP for the feral hog use. Let me know if you would like a more formal memo.

Thanks!

Elizabeth

Elizabeth Riley
Biologist, Environmental Risk Branch 6
Environmental Fate and Effects Division
United States Environmental Protection Agency

Jacobs, William

From: Riley, Elizabeth
Sent: Tuesday, September 03, 2013 1:23 PM
To: Jacobs, William
Subject: Feral Hog EUP Comments
Attachments: Comments on Feral Hog EUP.docx

Hi Bill,

I just realized that I forgot to send you the comments on the EUP for the feral hog use. Let me know if you would like a more formal memo.

Thanks!

Elizabeth

Elizabeth Riley
Biologist, Environmental Risk Branch 6
Environmental Fate and Effects Division
United States Environmental Protection Agency
703.347.0227

Comments on Feral Hog EUP

1. P. 7: "Place 25-100 pounds of bait into each feeder". Is there a maximum number of feeders that can be placed in a certain area?

2. P. 7: "Collect and properly dispose of all bait that may have spilled outside the feeder". For the purpose of the EUP, an effort should be made to measure the amount of bait that is spilled outside the feeder. This information could be used to quantify the potential for risk to non-targets.

3. P. 9: The Warfarin Toxicity Data table refers to chronic oral LD50 data as reported in Timm, 1994. Is it possible to view the underlying data sets and/or study designs?

4. P.12: "All test animals that consume the test product will be sampled to determine residue levels". How will samples be taken, analyzed and reported? This residue data will provide valuable information to assess potential secondary risks from feral hog uses. Individual measurements are preferred.

5. P. 15: "With multiple doses required, non-target poisoning is much less likely because the non-target animals will need to consume multiple doses in succession to receive a lethal dose". Label language requires the feeder be "refilled as needed, approximately every 2-5 days depending on number of feral hogs visiting the feeder" (p. 7). Based on this label language, spilled bait may be available for non-target animal consumption for up to 5 days, providing ample opportunity for multiple feedings. Quantification of spilled bait around the feeder would help reduce uncertainties associated with the potential for primary exposure and subsequent risks to non-target species.

6. P. 16: "The bait stations will be continuously monitored by motion activated camera to assure that non-target animals are unable to gain access to the bait". If non-target animals are observed gaining access to the bait, how will the HOGHOPPER or exposure scenario be modified to limit this? Again, an effort should be made to quantify spillage.

7. P. 16: "The bait is specifically designed for optimal palatability for feral hogs and as such it is likely that many non-target animals will not find it palatable". Are data available to support the palatability claims? The available efficacy study (Genesis Study Number N08019) mentions that strawberry flavoring is palatable to pigs but not other species but does not provide supporting references.

8. P. 16: "The bait stations will be regularly monitored and if spillage of bait is observed it will be removed to prevent non-target access". How frequently will stations be monitored? According to the label, the applicator is required to return to the site within 4 days after the initial application and at 2-5 day intervals. Based on this information, spilled bait may be available for non-target consumption for up to 5 days. Quantification of spilled bait around the feeder would help reduce uncertainties associated with this potential exposure.

9. P. 17. Primary risks analysis: Based on analyses conducted for the Scientific Advisory Panel (SAP) on the Notice of Intent to Cancel non-compliant rodenticide products, primary risks are still triggered for small, medium and large mammals from the proposed bait concentration for feral hogs. RQs range from 1.1 to 1.5, which are above the level of concern for listed and non-listed species. Quantification of spillage from bait stations will help reduce uncertainties associated with potential primary risks. Primary risks to birds are not anticipated.

10. P. 18: Half-life data: Available half-life data for the domesticated pic indicate a liver retention time of 30 to 40 days (O'Brien et al 1987). For other species the liver half-life ranges from 4 to 5 days.

11. P. 18: Secondary risks analysis: Based on analyses conducted for the SAP on the Notice of Intent to Cancel non-compliant rodenticide products, secondary risks are still triggered for small and large mammals from the proposed bait concentration for feral hogs. RQs range from 0.16 to 3.91, which are above the level of concern for listed and non-listed species. Residue levels in feral hogs resulting from the EUP will help reduce uncertainties associated with potential secondary risks from consumption of hog carcasses. Secondary risks to birds are not anticipated.

Decision #: 479666
DP #: (414617)
PRIA
Parent DP #:
Submission #: 936537
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 03-Sep-2013

* * * Registration Information * * *

Registration: 72500-EUP-E -

Company: 72500 - SCIMETRICS, LTD. CORP0RATION

Risk Manager: RM 07 - John Hebert - (703) 308-6249 Room# PY1 S-8641

Risk Manager Reviewer: William Jacobs BJACOBS

Sent Date: _____ PRIA Due Date: 03-Mar-2014 Edited Due Date: _____

Type of Registration: Experimental Use Permit - Sectio

Action Desc: (R251) EXPERIMENTAL USE PERMIT APPLICATION WHICH REQUIRES NO CHANGES TC

Ingredients: 086002, Warfarin(.005%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 15-Aug-2013 Due Back: _____

DP Ingredient: 086002, Warfarin

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: _____

	Assigned To	Date In	Date Out	
Organization:	RD / IRB			Last Possible Science Due Date: 03-Mar-2014
Team Name:				Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

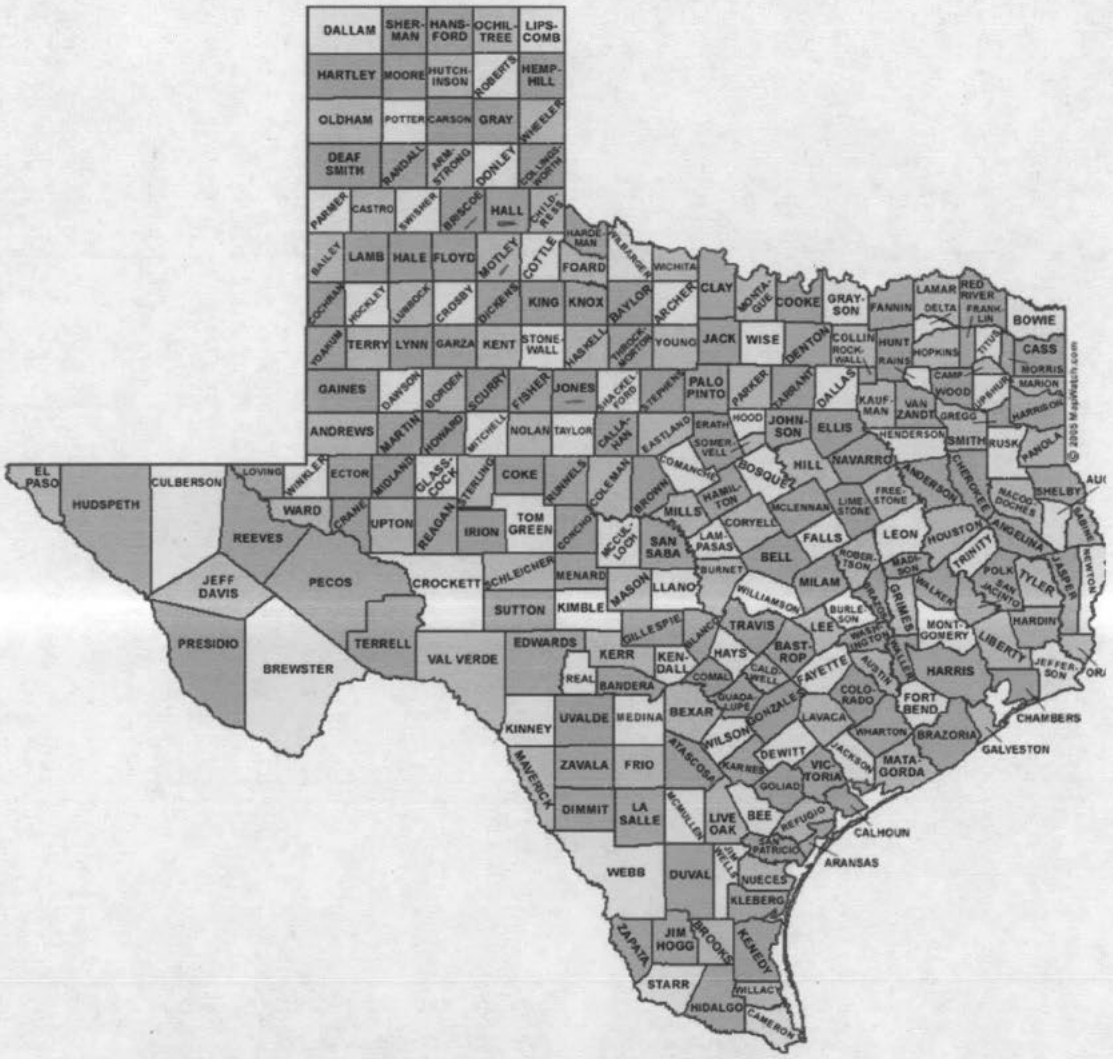
* * * Data Package Instructions * * *

Please review the pending experimental program, label, and CSF.

Digital-Topo-Maps.com

Texas County Map - Texas Map

AdChoices ▶ City Map ▶ County Map ▶ Highway Road Map ▶ Map Texas



More Detailed Maps Available

You may use the above map of Texas Counties on your website using the HTML code in the box below.
Please do not remove the attribution link or copyright information. Thank you.

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<img src="http://www.digital-topo-maps.com/county-map/texas-county-map.gif"><br>Map Courtesy of <a href="http://www.digital-topo-maps.com/county-map/texas.shtml">Digital-Topo-Maps.com</a>
```

State County Maps

United States Map
Alabama Counties
Alaska Counties
Arizona Counties
Arkansas Counties
California Counties
Colorado Counties
Connecticut Counties
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Georgia Counties
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North Dakota Counties
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Oklahoma Counties
Oregon Counties
Pennsylvania Counties
Rhode Island Counties
South Carolina Counties
South Dakota Counties
Tennessee Counties
Texas Counties
Utah Counties
Vermont Counties
Virginia Counties

S953705

Jacobs, William

From: sue@kaputproducts.com on behalf of Sue Valentine [sue@scimetricsltd.com]
Sent: Thursday, August 01, 2013 2:04 PM
To: Jacobs, William
Subject: EPA File Symbol 72500-EUP-E
Attachments: No.N08019 Novel Feral Hog Bait 12.23.08.pdf

Re: Your phone call on 7.31.13 regarding our EUP application for Feral Hog Bait dated June 7, 2013
EPA File Symbol 72500-EUP-E

Bill:
Please find attached final report of study no. N08019 "Development of a Novel Feral Hog (*Sus scrofa*) Bait". Page 9 of the study shows a summary of total mortality of feral hogs, including 100% mortality using bait with 0.005% warfarin. This information pertains to our EUP application listed above, Section E: Effectiveness Data.

Let me know if you have any questions or comments.
Thank you!
With best regards,
Sue.

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

Pages 102-159 Access to FIFRA Registration Data is restricted under FIFRA section 10(g)

Decision #: 479666
DP #: (413038)
PRIA
Parent DP #:
Submission #:
E-Sub #: 0

DATA PACKAGE BEAN SHEET

Date: 10-Jul-2013

* * * Registration Information * * *

Registration: 72500-EUP-E -

Company: 72500 - SCIMETRICS, LTD. CORP0RATION

Risk Manager: RM 07 - John Hebert - (703) 308-6249 Room# PY1 S-7227

Risk Manager Reviewer: William Jacobs BJACOBS

Sent Date: PRIA Due Date: Edited Due Date:

Type of Registration: Experimental Use Permit - Sectio

Action Desc:

Ingredients: 086002, Warfarin(.005%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 10-Jul-2013 Due Back:

DP Ingredient: 086002, Warfarin

DP Title:

CSF Included: ◯ Yes ● No Label Included: ◯ Yes ● No Parent DP #:

Assigned To	Date In	Date Out
Organization: EFED / ERB6		
Team Name:		
Reviewer Name:		
Contractor Name:		

Last Possible Science Due Date: 03-Mar-2014

Science Due Date:

Sub Data Package Due Date:

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please assign this EUP data package to the appropriate personnel.

Applicant requests permission to perform an experimental efficay trial over a large acreage of fenced land in Texas. Test material contains the anticoagulant rodenticide Warfarin at 0.005% a.i. and is to be applied in bait hoppers as an agent for controlling feral hogs. The bait strength is one-fifth of the level (0.025%) that commonly is used in rodenticide products containing Warfarin.

The application (enclosed) includes copies of the CSF and pending EUP label as well as a description of the planned field research.

Please comment on representations made in the application concerning ecological risks, on the pending label, and on other aspects of the application as appropriate.

Please indicate whether and which ecological effects data beyond those available for rodenticidal uses of Warfarin would be needed for registration of this type of product.

Decision #: 479666
DP #: (413046)
PRIA
Parent DP #:
Submission #: 936537
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 10-Jul-2013

* * * Registration Information * * *

Registration: 72500-EUP-E -

Company: 72500 - SCIMETRICS, LTD. CORP0RATION

Risk Manager: RM 07 - John Hebert - (703) 308-6249 Room# PY1 S-7227

Risk Manager Reviewer: William Jacobs BJACOBS

Sent Date: _____ PRIA Due Date: 03-Mar-2014 Edited Due Date: _____

Type of Registration: Experimental Use Permit - Sectio

Action Desc: (R251) EXPERIMENTAL USE PERMIT APPLICATION WHICH REQUIRES NO CHANGES TC

Ingredients: 086002, Warfarin(.005%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 10-Jul-2013 Due Back: _____

DP Ingredient: 086002, Warfarin

DP Title: _____

CSF Included: ○ Yes ● No Label Included: ○ Yes ● No Parent DP #: _____

	Assigned To	Date In	Date Out	
Organization:	HED / RAB6			Last Possible Science Due Date: 03-Mar-2014
Team Name:				Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Please assign this EUP data package to the appropriate personnel.

Applicant requests permission to perform an experimental efficacy trial in fenced land in Texas. Test material contains the anticoagulant rodenticide Warfarin at 0.005%, which is one-fifth the concentration at which it typically is used in rodenticide baits.

The application (enclosed) includes copies of the CSF and pending EUP label as well as a description of the planned field research.

Please comment on the representations made in the application concerning risks to humans and companion animals, on the pending label, and on other aspects of the application, as appropriate.

Please indicate whether and which health effects data beyond those available for rodenticide uses of Warfarin would be needed for registration of this type of product.

Bill Jacobs, 305-6406

To the Document Center (TRMD)

**Please transfer jacket/mini jacket to the Product Manager Team circled below:*

Minor Use Branch	PM 5		
IIAB:	PM 8		
Insect/Rodent Branch:	PM 1	(PM 7)	
Insecticide Branch:	PM 10	PM 13	
Fungicide Branch:	PM 20	PM 21	PM 22
Herbicide Branch:	PM 23	PM 25	

*Reminder to PM – If applicable, pick-up data from the Screening Room.

Steve Schaible
(Completeness Team Member Signature)

6/20/13
(Date)

Spec. Studies (at least for pch)

Thanks.

J —

1- Day Screen Completed by Contractor

Day Expires on 7/1/13

Jacket # 72500-EUP-E

MRID# n/A

n Screen: Recommend to Pass/Fail

Review: Pass/Fail/NA

ll Status: Recommend to Pass/Fail

Transfer This Jacket to:

Steve Schaible

07

87

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 6-10-13

Experts In-Processing Signature: B.B. Date 6-12-13 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date_____

EPA Reg. Number: 72500-EUP-E	EPA Receipt Date: 6-10-13

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					X
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					X
		yes	**no**			
	a) Selective Method (Fee category experts use)					
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**					X
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, reduced risk rationale**			X
	Required Data and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* No studies submitted.
* Inerts are approved for non-food use.
* Formulator's Exemption Statement was missing and the registrant sent it when requested.
* Jacket panel.

AB

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Sue Valentine
Phone #: 970 - 482-1330
Email: sue@scimetricsltd.com

Paneled

First Call/Initials: AB	Second Call/Initials:
Date: 06/19/13	Date:
Time: 1:32 PM	Time:

This is Aswathy Balan, EPA contractor.

I'm calling regarding your submission in support of
Rep# 72500-EUP-E.

We have found the following deficiencies regarding:
PR Notice 2011-3: Yes or (No)
Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or (No)

Application Package: (Yes) or No

* Formulator's Exemption Statement is missing.

These deficiencies have been approved by EPA.
The corrections can be faxed to 703-305-5060/Attn: Aswathy Balan

Second Call/Email:
If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.

Balan, Aswathy

From: sue@kaputproducts.com on behalf of Sue Valentine [sue@scimetricsltd.com]
Sent: Wednesday, June 19, 2013 2:18 PM
To: Balan, Aswathy
Subject: Re: Submission to EPA: Application for EUP- Kaput Feral Hog Bait (72500-EUP-E)
Attachments: FES Feral Hog EUP Appl.6.7.13.pdf

Dear Aswathy:
Thank you for your email. Please see attached Formulator's Exemption Statement. Let me know if you need anything else, or if you have any questions.
Thank you and best regards,
Sue.

On Wed, Jun 19, 2013 at 11:31 AM, Balan, Aswathy <Balan.Aswathy@epa.gov> wrote:

Dear Ms. Valentine,

This email is to address one issue found regarding your Application for experimental use permit of the product Kaput Feral Hog Bait. The Formulator's Exemption Statement is missing. Its required since the active source product is from a different company. You can send the form either by email or fax to 703-305-5060. Please contact me if you have any concerns.

Thanks,

Aswathy Balan
EPA Contractor
2777 S. Crystal Drive, S4811
Arlington, VA 22202
Ph: 703-347-8787
Fax: 703-305-5060

--
Sue Valentine
Scimetrics Ltd. Corp.
PO Box 1045
Wellington, CO 80549
Ph. 970-482-1330

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 11, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-479666
EPA File Symbol or Registration Number: 72500-EUP-E
Description: Experimental Use Permit for Kaput Feral Hog Bait
EPA Receipt Date: 10-Jun-2013
EPA Company Number: 72500
Company Name: SCIMETRICS, LTD. CORP0RATION

SUE VALENTINE
SCIMETRICS, LTD. CORP0RATION
PO Box 1045
WELLINGTON, CO 80549-1045

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code R251:

EXPERIMENTAL USE PERMIT APPLICATION WHICH REQUIRES NO CHANGES TO THE TOLERANCE(S);NON-CROP DESTRUCT BASIS;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{936537B~

This package includes the following

- ◉ New Registration
- ○ Amendment

☐ Studies? ☑ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S- 936537

EPA File Symbol/Reg. No. 72500-EUP-E

Pin-Punch Date: 6/10/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R251

Granted: R251

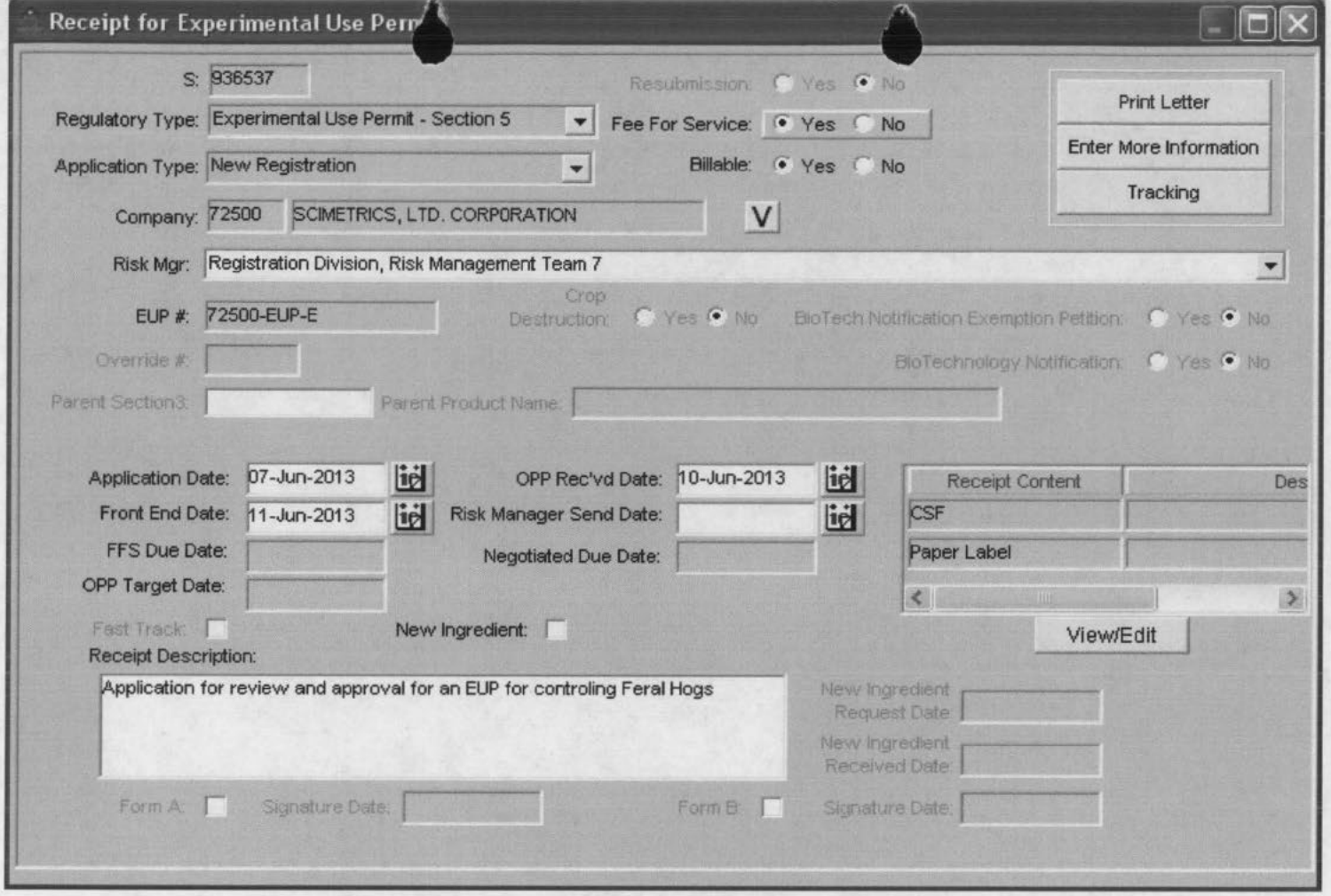
Amount Due: $ 17,993. ea

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: _____ Date: 6-11-13

Remarks:


Receipt for Experimental Use Perm
S: 936537
Resubmission: Yes No
Regulatory Type: Experimental Use Permit - Section 5
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 72500 SCIMETRICS, LTD. CORPORATION
V
Risk Mgr: Registration Division, Risk Management Team 7
EUP #: 72500-EUP-E
Crop Destruction: Yes No
BioTech Notification Exemption Petition: Yes No
Override #:
BioTechnology Notification: Yes No
Parent Section3:
Parent Product Name:
Application Date: 07-Jun-2013
OPP Rec'vd Date: 10-Jun-2013
Front End Date: 11-Jun-2013
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
CSF
Paper Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Application for review and approval for an EUP for controling Feral Hogs
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

SCIMETRICS LTD CORP. 10465

US ENVIRONMENTAL ECTION

k Number: 10465
heck Date: May 28, 2013

Check Amount: $4,498.00

Item to be Paid - Description	Discount Taker	Amount Paid
Feral Hog		4,498.00

Commercial/financial information may be entitled to confidential treatment

10465

SCIMETRICS LTD CORP.
9974 N.E. FRONTAGE RD.
P.O. BOX 1045
WELLINGTON, CO 80549
PH. (970) 482-1330

COPY

FARMERS BANK
AULT, CO 80610
82-7409-3070

May 28, 2013 (DATE) ***$4,498.00 (AMOUNT)

Memo:

Four Thousand Four Hundred Ninety-Eight and 00/100 Dollars

PAY TO THE ORDER OF US ENVIRONMENTAL PROTECTION AGENCY

Rebecca Rocha
AUTHORIZED SIGNATURE

For: EUP Feral Hogs

⑈010465⑈ [redacted]

881013 / 07-08

Security features. Details on back.

SCIMETRICS LTD CORP. 10465

US ENVIRONMENTAL PROTECTION

Check Number: 10465
Check Date: May 28, 2013

Check Amount: $4,498.00

Item to be Paid - Description	Discount Taker	Amount Paid
Feral Hog EUP		4,498.00

DELUXE CORP 1+800-328-0304 www.deluxeforms.com

Scimetrics
LTD. CORP.

June 7, 2013

Mr. John Hebert, PM#7
Document Processing Desk – **REGFEE**
Office of Pesticide Programs – 7504P
U.S. Environmental Protection Agency
One Potomac Yard (South Building), Rm S-4900
2777 South Crystal Drive
Arlington, VA 22202

Dear Mr. Hebert:

Subject: Application for Experimental Use Permit
Kaput Feral Hog Bait

Scimetrics Ltd. Corp. is submitting the enclosed documents for review and approval of an Experimental Use Permit for controlling Feral Hogs as discussed with Mr. John Hebert during our meeting at the Agency on April 17, 2013.

Enclosed are the following:

Administrative Documents:

1. A copy of the PRIA fee payment for Experimental Use Permit, Category R251 (check no. 10465 for $4498) is attached to:
2. Application for Experimental Use Permit
3. Voluntary Small Business Certification Form for Pesticide Registration Fee Waiver
4. Waiver Re-certification Statement Letter
5. Five (5) copies of proposed labeling
6. Three (3) copies of Confidential Statement of Formula
7. Three (3) copies of application documentation Section A-G

Scimetrics is requesting this experimental use permit for the purpose of testing the field efficacy of Kaput Feral Hog Bait in Texas for controlling feral hog populations.

Scimetrics
LTD. CORP.
PO Box 1045 • Wellington, Colorado 80549-1045
970-482-1330 Phone • 970-482-1885 Fax
www.kaputproducts.com

Please contact us if you have any questions or if you need any other information at this time.
Contact Information: Sue Valentine, Ph. 970-482-1330, email: sue@scimetricsltd.com

Sincerely,

Sue Valentine

Sue Valentine
Regulatory Manager

Encl.

☆ U.S. GOVERNMENT PRINTING OFFICE: 1999 – 452-584/25008

Form Approved. OMB No. 2070-0040.

OPP Identifier Number

United States
ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

Office of Pesticides Programs (7505C)

Application for Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only

1. Type of Application

☒ New ☐ Amendment (See No. 2)

☐ Extension *(Give Permit Number below)*

Permit Number

2. Briefly explain (attach a separate sheet if necessary)

We are requesting an experimental use permit for the purpose of testing the field efficacy of Kaput® Feral Hog Bait for controling feral hog populations. The bait is to be used with feral hog bait stations that allow access to feral hogs but prevent non-target animals from accessing bait.

3. Name and Address of Firm/Person to Whom the Experimental Use Permit is to be Issued (include Zip Code) *(Type or Print)*

Scimetrics, Ltd. Corp.
9974 N.E. Frontage Rd.
Wellington, CO 80549

4. Name and Address of Shipper only if shipment is intended or if different from applicant's name and address (include Zip Code) *(Type or Print)*

EPA Company Number 72500

5. Name of Product

Kaput® Feral Hog Bait

6. Is Product Registered with EPA?

☒ No

☐ Yes (Give Registration Number or File Symbol below)

Registration Number _____

File Symbol _____

7. Total Quantity of Product Proposed for Shipment/Use

Pounds of formulated product 12,600

Pounds of active ingredient 1

8. Acreage or Area to be Treated

1- 10 square kilometers
(equals 247-2,471 acres)

9. Proposed Period of Shipment/Use

July through August of 2014

10. Places from which Shipped

Scimetrics Ltd. Corp
Wellington, CO 80549

11. Crop/Site to be Treated

Texas: Hall, Motley, Jones, or Briscoe counties

12. Specify the name and number of the contact person most familiar with this application.

Sue Valentine
970-482-1330
sue@scimetricsltd.com

13. Signature of Applicant or Authorized Firm Representative

Sue Valentine

14. Title
Regulatory Manager

15. Date Signed
06/07/2013

Certification

This is to certify that food or feed derived from the experimental program will not be used or offered for consumption or sale for consumption, except by laboratory or experimental animals, if illegal residues are present in or on such food or feed.

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment, or both, under applicable law.

Below for EPA Use Only

In any correspondence on this application, refer to this number

Received by:
EPA-OPP Registration Division,
Washington, DC 20460

Normal review time indicates that processing of this application should be completed by (date)

Name of EPA Contact Person

Telephone Number

EPA Form 8570-17 (Rev. 1-94) Previous Editions are Obsolete

Form Approved. OMB Nos. 2070-0060, 2070-0057, 2070-107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement
(40 CFR § 152.85 and § 158.50)

Applicant's Name and Address:	EPA File Symbol/Registration Number: 72500-__
Scimetrics Ltd. Corporation **P.O. Box 1045** **Wellington, CO 80549**	Product Name: **Kaput Feral Hog Bait**
	Date of Confidential Statement of Formula (*EPA Form 8570-4*): **June 7, 2013**

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Warfarin @ 0.005%

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR § 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (CSF) (*EPA Form 8570-4*) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name the source of the active ingredient(s) listed in paragraph (1).

☐ (B) The Confidential Statement of Formula (CSF) (*EPA Form 8570-4*) referenced above and on file with the EPA is complete, current, is accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the Formulator's Exemption:

Active Ingredient(s)	Source Product Name(s)	Registration Number(s)
Warfarin	[redacted]	

Signature	Name and Title	Date
Sue Valentine	**Sue Valentine** **Regulatory Manager**	**June 7, 2013**

EPA Form 8570-27 (Rev. 06-2004)

Product ingredient source information may be entitled to confidential treatment

FOR EXPERIMENTAL USE ONLY
Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program.

Kaput® Feral Hog Bait

Active Ingredient:	
Warfarin (CAS Number 81-81-2)	0.005%
Other Ingredients	99.995%
Total	100.000%

Keep Out of Reach of Children
CAUTION
See back [side] panel for First Aid and additional Precautionary Statements.

EUP No. _____ EPA Est. 72500-CO-1

Net Wt. _____ lbs.
{25 lbs. - 100 lbs.}
[11.34 kg – 45.36 kg]

{Back/Side/Below}

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
This label must be in the user's possession at the time of product application.

READ THIS LABEL:
Read this entire label and follow all use directions and use precautions.
IMPORTANT: Do not expose children, pets, domesticated animals or other non-target wildlife to this product. To help prevent accidents:

1. Store product not in use in locations out of reach of children, pets, domesticated animals and wildlife.
2. Apply this product only as specified on this label.
3. Dispose of product container as well as unused, spoiled, or recoverable unconsumed bait, as specified on this label.

USE RESTRICTIONS: This product may be used to control only feral hogs (*Sus scrofas*) on rangeland, forests, non-crop areas, and crop lands.

- Do not apply this bait on the ground.
- Use a HOGHOPPER™ feeder or similar feeder with heavy lid that prevents non-target animals from accessing the bait.
- Apply bait in fenced areas and avoid application in open range areas.
- Wear protective gloves when handling bait or animal carcasses.
- Store this product out of reach and away from humans, domesticated animals, pets and wildlife.

- Do not allow young children, pets, domesticated animals or persons not associated with the application to be in areas where the bait is being applied.

SITE ASSESSMENT: Before applying this product, observe the area to identify where feral hog activity and trails are evident. Look for damaged crops, rutting of the soil and tracks to ensure activity in the area.

BAIT APPLICATION: Place 25-100 pounds of bait into each feeder. The animal access door must be closed limiting access only to feral hogs. Treatment should continue for 10-21 days and the feeder monitored and refilled as needed, approximately every 2-5 days depending on number of feral hogs visiting the feeder. **Leave no bait on soil surface or outside the feeder.** Collect and properly dispose of all bait that may have spilled outside the feeder. After treatment, collect and properly dispose of any bait that may have fallen out of the feeder.

SURVEILLANCE AND FOLLOW UP: Dead feral hogs may begin to appear in or near the treatment areas within 4-7 days after bait placement. Applicators must return to the treatment site within 4 days of application, and at 2-5 day intervals thereafter, to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface. All carcasses found must be collected and disposed of properly. Bury carcasses on site in holes dug at least 18 inches deep. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by other methods to insure that carcasses are inaccessible to scavengers. Continue to collect and dispose of feral hogs and search for non-target animals for at least two weeks after the last filling of the bait feeder boxes. Deaths of any animals other than feral hogs, that appear to be the result of baiting, must be reported to state authorities.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available, or reconditioning, if appropriate; otherwise, dispose of empty container in a sanitary landfill.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Keep away from humans, domestic animals and pets. Any person who retrieves carcasses or unused bait following application of this product must wear protective gloves.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Poison Information Center at 1-800-858-7378 for emergency medical treatment information.

If swallowed, immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in eyes, hold eye open and rise slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN

Contains Warfarin, an anticoagulant. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or animals that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS

This product may be toxic to fish, birds and other wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait. Do not apply this product directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash waters.

Manufactured by:

Scimetrics
LTD. CORP.
New Solutions to Old Problems

[Pest Management Solutions]
P.O. Box 1045
Wellington, CO 80549
(970) 482-1330
customerservice@kaputproducts.com
Made in USA

{ } Denotes language that does not appear on the market label
[ ] Denotes alternate language

FOR EXPERIMENTAL USE ONLY
Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program.

Kaput® Feral Hog Bait

Active Ingredient:	
Warfarin (CAS Number 81-81-2)	0.005%
Other Ingredients	99.995%
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for First Aid and additional Precautionary Statements.

EUP No. _____ EPA Est. 72500-CO-1

Net Wt. _____ lbs.
{25 lbs. - 100 lbs.}
[11.34 kg – 45.36 kg]

{Back/Side/Below}

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
This label must be in the user's possession at the time of product application.

READ THIS LABEL:
Read this entire label and follow all use directions and use precautions.
IMPORTANT: Do not expose children, pets, domesticated animals or other non-target wildlife to this product. To help prevent accidents:

1. Store product not in use in locations out of reach of children, pets, domesticated animals and wildlife.
2. Apply this product only as specified on this label.
3. Dispose of product container as well as unused, spoiled, or recoverable unconsumed bait, as specified on this label.

USE RESTRICTIONS: This product may be used to control only feral hogs (*Sus scrofas*) on rangeland, forests, non-crop areas, and crop lands.

- Do not apply this bait on the ground.
- Use a HOGHOPPER™ feeder or similar feeder with heavy lid that prevents non-target animals from accessing the bait.
- Apply bait in fenced areas and avoid application in open range areas.
- Wear protective gloves when handling bait or animal carcasses.
- Store this product out of reach and away from humans, domesticated animals, pets and wildlife.

- Do not allow young children, pets, domesticated animals or persons not associated with the application to be in areas where the bait is being applied.

SITE ASSESSMENT: Before applying this product, observe the area to identify where feral hog activity and trails are evident. Look for damaged crops, rutting of the soil and tracks to ensure activity in the area.

BAIT APPLICATION: Place 25-100 pounds of bait into each feeder. The animal access door must be closed limiting access only to feral hogs. Treatment should continue for 10-21 days and the feeder monitored and refilled as needed, approximately every 2-5 days depending on number of feral hogs visiting the feeder. **Leave no bait on soil surface or outside the feeder.** Collect and properly dispose of all bait that may have spilled outside the feeder. After treatment, collect and properly dispose of any bait that may have fallen out of the feeder.

SURVEILLANCE AND FOLLOW UP: Dead feral hogs may begin to appear in or near the treatment areas within 4-7 days after bait placement. Applicators must return to the treatment site within 4 days of application, and at 2-5 day intervals thereafter, to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface. All carcasses found must be collected and disposed of properly. Bury carcasses on site in holes dug at least 18 inches deep. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by other methods to insure that carcasses are inaccessible to scavengers. Continue to collect and dispose of feral hogs and search for non-target animals for at least two weeks after the last filling of the bait feeder boxes. Deaths of any animals other than feral hogs, that appear to be the result of baiting, must be reported to state authorities.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available, or reconditioning, if appropriate; otherwise, dispose of empty container in a sanitary landfill.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Keep away from humans, domestic animals and pets. Any person who retrieves carcasses or unused bait following application of this product must wear protective gloves.

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If swallowed, immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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If animal eats bait, call veterinarian at once.

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ENVIRONMENTAL HAZARDS

This product may be toxic to fish, birds and other wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait. Do not apply this product directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash waters.

Manufactured by:

Scimetrics
LTD. CORP.
New Solutions to Old Problems

[Pest Management Solutions]
P.O. Box 1045
Wellington, CO 80549
(970) 482-1330
customerservice@kaputproducts.com
Made in USA

{ } Denotes language that does not appear on the market label
[ ] Denotes alternate language

FOR EXPERIMENTAL USE ONLY
Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program.

Kaput® Feral Hog Bait

Active Ingredient:	
Warfarin (CAS Number 81-81-2)	0.005%
Other Ingredients	99.995%
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for First Aid and additional Precautionary Statements.

EUP No. _____ EPA Est. 72500-CO-1

Net Wt. _____ lbs.
{25 lbs. - 100 lbs.}
[11.34 kg – 45.36 kg]

{Back/Side/Below}

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Read this entire label and follow all use directions and use precautions.
IMPORTANT: Do not expose children, pets, domesticated animals or other non-target wildlife to this product. To help prevent accidents:

1. Store product not in use in locations out of reach of children, pets, domesticated animals and wildlife.
2. Apply this product only as specified on this label.
3. Dispose of product container as well as unused, spoiled, or recoverable unconsumed bait, as specified on this label.

USE RESTRICTIONS: This product may be used to control only feral hogs (*Sus scrofas*) on rangeland, forests, non-crop areas, and crop lands.

- Do not apply this bait on the ground.
- Use a HOGHOPPER™ feeder or similar feeder with heavy lid that prevents non-target animals from accessing the bait.
- Apply bait in fenced areas and avoid application in open range areas.
- Wear protective gloves when handling bait or animal carcasses.
- Store this product out of reach and away from humans, domesticated animals, pets and wildlife.

- Do not allow young children, pets, domesticated animals or persons not associated with the application to be in areas where the bait is being applied.

SITE ASSESSMENT: Before applying this product, observe the area to identify where feral hog activity and trails are evident. Look for damaged crops, rutting of the soil and tracks to ensure activity in the area.

BAIT APPLICATION: Place 25-100 pounds of bait into each feeder. The animal access door must be closed limiting access only to feral hogs. Treatment should continue for 10-21 days and the feeder monitored and refilled as needed, approximately every 2-5 days depending on number of feral hogs visiting the feeder. **Leave no bait on soil surface or outside the feeder.** Collect and properly dispose of all bait that may have spilled outside the feeder. After treatment, collect and properly dispose of any bait that may have fallen out of the feeder.

SURVEILLANCE AND FOLLOW UP: Dead feral hogs may begin to appear in or near the treatment areas within 4-7 days after bait placement. Applicators must return to the treatment site within 4 days of application, and at 2-5 day intervals thereafter, to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface. All carcasses found must be collected and disposed of properly. Bury carcasses on site in holes dug at least 18 inches deep. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by other methods to insure that carcasses are inaccessible to scavengers. Continue to collect and dispose of feral hogs and search for non-target animals for at least two weeks after the last filling of the bait feeder boxes. Deaths of any animals other than feral hogs, that appear to be the result of baiting, must be reported to state authorities.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available, or reconditioning, if appropriate; otherwise, dispose of empty container in a sanitary landfill.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Keep away from humans, domestic animals and pets. Any person who retrieves carcasses or unused bait following application of this product must wear protective gloves.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Poison Information Center at 1-800-858-7378 for emergency medical treatment information.

If swallowed, immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in eyes, hold eye open and rise slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN

Contains Warfarin, an anticoagulant. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or animals that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS

This product may be toxic to fish, birds and other wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait. Do not apply this product directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash waters.

Manufactured by:

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LTD. CORP.
New Solutions to Old Problems

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[ ] Denotes alternate language

FOR EXPERIMENTAL USE ONLY
Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program.

Kaput® Feral Hog Bait

Active Ingredient:	
Warfarin (CAS Number 81-81-2)	0.005%
Other Ingredients	99.995%
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for First Aid and additional Precautionary Statements.

EUP No. _____ EPA Est. 72500-CO-1

Net Wt. _____ lbs.
{25 lbs. - 100 lbs.}
[11.34 kg – 45.36 kg]

{Back/Side/Below}

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
This label must be in the user's possession at the time of product application.

READ THIS LABEL:
Read this entire label and follow all use directions and use precautions.
IMPORTANT: Do not expose children, pets, domesticated animals or other non-target wildlife to this product. To help prevent accidents:

1. Store product not in use in locations out of reach of children, pets, domesticated animals and wildlife.
2. Apply this product only as specified on this label.
3. Dispose of product container as well as unused, spoiled, or recoverable unconsumed bait, as specified on this label.

USE RESTRICTIONS: This product may be used to control only feral hogs (*Sus scrofas*) on rangeland, forests, non-crop areas, and crop lands.

- Do not apply this bait on the ground.
- Use a HOGHOPPER™ feeder or similar feeder with heavy lid that prevents non-target animals from accessing the bait.
- Apply bait in fenced areas and avoid application in open range areas.
- Wear protective gloves when handling bait or animal carcasses.
- Store this product out of reach and away from humans, domesticated animals, pets and wildlife.

- Do not allow young children, pets, domesticated animals or persons not associated with the application to be in areas where the bait is being applied.

SITE ASSESSMENT: Before applying this product, observe the area to identify where feral hog activity and trails are evident. Look for damaged crops, rutting of the soil and tracks to ensure activity in the area.

BAIT APPLICATION: Place 25-100 pounds of bait into each feeder. The animal access door must be closed limiting access only to feral hogs. Treatment should continue for 10-21 days and the feeder monitored and refilled as needed, approximately every 2-5 days depending on number of feral hogs visiting the feeder. **Leave no bait on soil surface or outside the feeder.** Collect and properly dispose of all bait that may have spilled outside the feeder. After treatment, collect and properly dispose of any bait that may have fallen out of the feeder.

SURVEILLANCE AND FOLLOW UP: Dead feral hogs may begin to appear in or near the treatment areas within 4-7 days after bait placement. Applicators must return to the treatment site within 4 days of application, and at 2-5 day intervals thereafter, to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface. All carcasses found must be collected and disposed of properly. Bury carcasses on site in holes dug at least 18 inches deep. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by other methods to insure that carcasses are inaccessible to scavengers. Continue to collect and dispose of feral hogs and search for non-target animals for at least two weeks after the last filling of the bait feeder boxes. Deaths of any animals other than feral hogs, that appear to be the result of baiting, must be reported to state authorities.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available, or reconditioning, if appropriate; otherwise, dispose of empty container in a sanitary landfill.

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Keep away from humans, domestic animals and pets. Any person who retrieves carcasses or unused bait following application of this product must wear protective gloves.

FIRST AID

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If **swallowed,** immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in eyes, hold eye open and rise slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN

Contains Warfarin, an anticoagulant. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or animals that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS

This product may be toxic to fish, birds and other wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait. Do not apply this product directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash waters.

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EXPERIMENTAL USE PERMIT APPLICATION

BY:

Scimetrics Ltd. Corp.
Wellington, CO 80549

TITLE:

Field Efficacy of Kaput® Feral Hog Bait for Population Control of Feral Hog (Sus scrofa) in Texas

DATE OF APPLICATION:

June 7, 2013

MAIN CONTACT:

Sue Valentine
Scimetrics Ltd. Corp.
P.O. Box 1045
Wellington, CO 80549
Ph. 970-482-1330
sue@scimetricsltd.com

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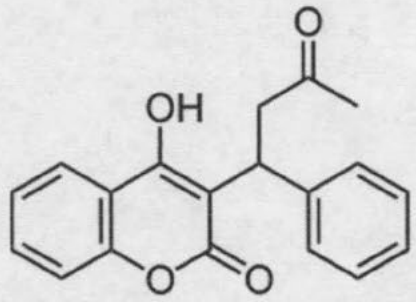
Section A: Chemical and Physical Properties of Test Chemical and Statement of Formulation of Active and Inert Ingredients.

TEST CHEMICAL: Warfarin $C_{19}H_{16}O_4$ (M.W. 308.4g)



NOMENCLATURE: Common name warfarin (BSI, E-ISO, BAN); warfarine ((m) F-ISO); coumafène (France); zoocoumarin (USSR); coumarins (JMAF, also applied to coumatetralyl *(q.v.));* no name (The Netherlands).
IUPAC name (RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin;
3- *(α* -acetonyl benzyl) -4-hydroxycoumarin
Chemical Abstracts name 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-1-benzopyran-2-one
Other names coumaphene
CAS RN *[81-81-2]* unstated stereochemistry; *[5543-58-8]* (R)-(+)-
isomer; *[5543-57-7]* (S)-(-)- isomer EC no. 201-377-6 *(RS)·* isomers; 226-908-9 *(R)·* isomer; 226-907-3 (S)- isomer

PHYSICAL CHEMISTRY: Mol. wt. 308.3 M.f. $C_{19}H_{16}0_4$
Form The racemate forms colourless crystals. **M.p.**161-162°C **V.p.**1.5 x 10^{-3} mPa **Solubility** In water 17 mg/l (20°C). Very slightly soluble in benzene, diethyl ether and cyclohexane. Moderately soluble in methanol, ethanol and isopropanol. In acetone 65, chloroform 56, dioxane 100 (all in g/1, 20°C). Dissolves in aqueous alkalis with the formation of water-soluble salts. Sodium salt: in water up to 400 g/1; insoluble in organic solvents. **Stability** Very stable, even to strong acids. **pKa** It is acidic

APPLICATIONS: Biochemistry General internal bleeding is induced by reduction of the prothrombin content of the blood. **Mode of action** Anticoagulant rodenticide. Repeated ingestion is necessary to produce toxic symptoms. The (5)-(-)- isomer has 7-fold greater rodenticidal activity than the (R)-(+)- isomer (B. D. West et al., J. *Am. Chem. Soc.*, 1961, 83, 2676). **Uses** Control of rats and mice; also control of grey squirrels for tree protection, by presentation of bait in special hoppers. There is no tendency to bait-shyness. **Compatibility** Compatible with other rodenticides.

Confidential Statement of Formula may be entitled to confidential treatment

Section B: Proposed Experimental Label

FOR EXPERIMENTAL USE ONLY
Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program.

Kaput® Feral Hog Bait

Active Ingredient:	
Warfarin (CAS Number 81-81-2)	0.005%
Other Ingredients	99.995%
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for First Aid and additional Precautionary Statements.

EUP No. _____ EPA Est. 72500-CO-1

Net Wt. _____ lbs.
{25 lbs. - 100 lbs.}
[11.34 kg – 45.36 kg]

{Back/Side/Below}

DIRECTIONS FOR USE

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READ THIS LABEL:
Read this entire label and follow all use directions and use precautions.
IMPORTANT: Do not expose children, pets, domesticated animals or other non-target wildlife to this product. To help prevent accidents:

1. Store product not in use in locations out of reach of children, pets, domesticated animals and wildlife.
2. Apply this product only as specified on this label.
3. Dispose of product container as well as unused, spoiled, or recoverable unconsumed bait, as specified on this label.

USE RESTRICTIONS: This product may be used to control only feral hogs (*Sus scrofas*) on rangeland, forests, non-crop areas, and crop lands.

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STORAGE AND DISPOSAL

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PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

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FIRST AID

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If animal eats bait, call veterinarian at once.

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Section C: Toxicity Data

Warfarin Toxicity Data

Species	Acute Oral LD50 (mg/kg)[1]	Chronic Oral LD50 (mg/kg/day)[1]
Mouse	374	0.6 for 3-9 days
Rat	3.0	0.4 for 4-15 days
Rat	50-100	1 for 5 days
Rabbit	800	30.0 for 6-15 days
Swine	3	0.05 for 7 days
Dog	20-50	5 for 5-15 days
Cat	6-40	3.0-5.0 for 10 days
Cat	5-50	1for 5 days
Ruminants	-	200 for 12 days
Chicken	1000	-

[1] Timm, R. M. 1994 Vertebrate Pesticides. Pages G26-G29 In (S.E. Hyngstrom, R. M. Timm, and G. E. Larson, eds.) Prevention and Control of Wildlife Damage. University of Nebraska Cooperative Extension.

Adjusted Toxicity Data for Warfarin Concentration Found in Bait

Species	Acute Oral LD50 (mg of Bait/kg)	Chronic Oral LD50 (mg of Bait/kg/day)
Mouse	7,480,000	12,000 for 3-9 days
Rat	60,000	8,000 for 4-15 days
Rat	1,000,000-2,000,000	20,000 for 5 days
Rabbit	16,000,000	600,000 for 6-15 days
Swine	60,000	1,000 for 7 days
Dog	400,000-1,000,000	100,000 for 5-15 days
Cat	120,000-800,000	60,000-100,000 for 10 days
Cat	100,000-1,000,000	20,000 for 5 days
Ruminants	-	4,000,000 for 12 days
Chicken	20,000,000	-

MAMMALIAN TOXICOLOGY: **Oral** Acute oral LD50 for rats 186, mice 374 mg/kg. Oral LD50 for rats 1, pigs 1, cats 3, dogs 3, cattle 200 (all mg/kg daily for 5 days). **ADI/RID** (EC) Not applicable [2006]; (EPA) cRfD 0.0003 mg/kg b.w. [1988]. **Other** Organ damage is observed, as well as inhibition of blood coagulation. Only slightly dangerous to humans and domestic animals when used as directed, but care must be taken with young pigs, which are especially susceptible. **Toxicity class** WHO (a.i.) lb; EPA (formulation) I. **EC classification** R611 T; R48/251 R52, R53 for (R)-, (5)-, or (RS)- isomers).

Section D: Residue Data

Not applicable – Studies will be completed on rangelands and the product will be applied in a HOGHOPPER™ or similar feral hog specific feeder.

Section E: Effectiveness Data

The effectiveness of this product will be determined by the data generated from this EUP research. However, previous studies conducted by Genesis Laboratories, Inc. have shown 100 % efficacy of a 0.005 % warfarin feral hog bait in pen trials. The acute LD50for warfarin in swine is 3 mg/kg for single dose or 0.05 mg/kg for 7 days. In light of this data we are confident that bait formulations used in this EUP research will be shown to be effective.

Section F: Tolerance Data

There are no EPA Maximum Residue Levels for residues of warfarin in food or feed. The product will be applied in a manner to prevent contact with vegetation or crops. All test animals that consume the test product will be sampled to determine residue levels. [redacted] will also be evaluated on test animals as a preventative against human consumption of exposed animals. The test animals will be disposed to prevent any consumption of test animals.

Inert ingredient information may be entitled to confidential treatment

Section G: Proposed Experimental Program

1. Participants and Collaborators

Field testing using Kaput® Feral Hog Bait containing 0.005% warfarin will be organized and completed by Genesis Laboratories, Inc. having its principle place of business at 10122 N.E. Frontage Rd., Wellington, CO 80549. All major participants in this study will be University graduates with backgrounds in biology wildlife biology or associated field. The key participants are:

Richard M. Poché	President and Technical Manager of Genesis Laboratories, Inc. with an M.S. in Wildlife Biology and over 40 years of experience in pest control product development. I have conducted research in over 50 countries including projects in wildlife management and management of invasive and pest species. I have led development of several pest and vector management products which includes acquiring patents and bringing products to market.
Robyn R. Raban	Senior Vector Ecologist at Genesis Laboratories, Inc. with M.S. in Medical Entomology and Ph.D. candidate in Vector Biology and Arbovirology. Has been the principal investigator for multiple vector control projects.
Christopher S. DePerno	Associate Professor, Fisheries, Wildlife, and Conservation Biology at North Carolina State University. Certified Wildlife Biologist with over 22 year of experience and over six years of experience conducting feral hog disease research.
Kevin J. Aldrich	Biologist/Assistant Lab Manager at Genesis Laboratories, Inc. with a M.S. in Biology and over 12 years of laboratory and research experience. I have conducted research in, wildlife management, animal disease diagnostics, swine epidemiology research, and ecotoxicology research. I have been the study director for multiple animal research projects and have extensive experience as an Institutional Animal Care and Use Committee (IACUC) chairperson.

2. State in Which Product will be used

This study will be conducted in the state of Texas with final field locations yet to be determined. The field sites will be determined based on sufficient numbers of feral hogs and perimeter fencing to eliminate human disturbance to field sites.

The treatment area will be approximately 1- 10 km^2 depending of feral hog densities. Study site will be chosen to ensure 50 to 100 feral hogs. The treatment area will not exceed 10 km^2. The total amount of bait applied will not exceed 10,000lbs.

3.

Target Species	Feral hog (Sus scrofa)
Location of Study	Texas: Hall, Motley, Jones, or Briscoe counties.
Sites of Application	Bait will be applied in feeders located at sites with active feral hog sign. The feeders will be spaced to limit duplicate hog visitation.
Desire Time of Application	Bait may be applied from spring to summer and not overlapping big game hunting seasons.
Use Pattern	Bait stations will be regularly monitored and will be kept filled for the duration of the 3 week experimental phase of the study.
Plot Size	Not to exceed 10 km^2 or 2,471 acres.
Dose Rate	Ad libitum. 25-100 lbs. of bait will be applied to each bait station.
Frequency of Application	Bait stations will be refilled as needed for the duration of the 3 week experimental phase. Approximately every 3-4 days.
Method of Application	Bait will be presented in feeders designed to restrict access animals other than feral hogs.
Season of Use	Late spring, summer, or early fall.
Amount of bait required	Kaput® Feral Hog Bait maximum amount required =12,600 lbs.
Amount of Active Required	0.63 lbs. warfarin.
Disposition of Unused Bait	Genesis Laboratories, Inc. will arrange to have unused bait incinerated.

4. Information on Prior Testing.

Previous work conducted at Genesis Laboratories, Inc. has provided preliminary data needed for this field study. In pen trials several bait concentrations were evaluated for efficacy as a feral hog bait. Baits with warfarin concentrations of 0.025% were found to have 100% efficacy when fed for 2 days. Baits with warfarin concentrations of 0.0125% were found to have 100% efficacy when fed for 5 days. Baits with warfarin concentrations of 0.005% were found to have 100% efficacy when fed for 5 days. Based on these results it was determined that bait with 0.005% warfarin would be effective and reduce any risk to non-target animals.

A 0.005 % warfarin bait such as Kaput® Feral Hog Bait provides several advantages. With anticoagulant baits such as this symptoms of poisoning will not develop until after a lethal dose is consumed preventing development of bait shyness(Godfrey & Lyman, 1980). Therefore, baits can be used that require multiple feedings to provide a lethal dose. Because the warfarin bait lends itself to multiple feedings it allows for the dose to be reduced drastically which will reduce risk to non-target animals. With multiple doses

required, non-target poisoning is much less likely because the non-target animals will need to consume multiple doses in succession to receive a lethal dose. In the same manner multiple doses reduce the risks of secondary.

5. Objectives of the proposed EUP program

The objectives of the proposed study are to determine the following:

A. To determine the efficacy of Kaput® Feral Hog Bait for control of feral hogs, containing 0.005% warfarin, when presented in HOGHOPPER™ feral hog feeders in a field setting.

B. To generate product performance data in support of FIFRA registration for Kaput® Feral Hog Bait for control of feral hogs.

C. To generate safety data during field use of product including; preventing non-target animal exposure by using hog specific bait station, preventing potential human exposure by evaluating [redacted] presence in baited animals, and determining secondary exposure risk by evaluating residue levels in tissues of baited animals.

6. Justification of Quantity of Material Requested

The material requested was calculated by estimating the consumption for an average size feral hog at approximately 100 lbs. A hog this size would typically need about 5-6 lbs. of grain per day. Therefor for a maximum of 100 hogs that consume 6 lbs. bait per day for the maximum of 21 days of treatment we will use a maximum of 12,600 lbs. The actual amount used will not exceed 12,600 lbs. and will be monitored and documented. Any excess test material will be incinerated.

7. Duration of the EUP program

The study will include a pre-exposure census of approximately 3 weeks. During this time a passive tracking index will be calculated following the method described by (Engeman, Constantin, Nelson, Woolard, & Bourassa, 2001). Additional census methods may be employed as needed depending or terrain and population densities. The exposure period will be conducted directly following the pre-exposure census and will last up to 3 weeks. Following the exposure period there will be a 3 week post-exposure census. The total duration of the experimental phase of the study will be approximately 9 weeks with up to 3 weeks of bait application. The duration may be longer if data justify a need for additional study.

Inert ingredient information may be entitled to confidential treatment

Study Phase	Approximate Duration
Pre-exposure census	3 Weeks
Exposure period	3 Weeks
Post-exposure census	3 Weeks

8. Disposition of any Unused Material

Any remaining Kaput® Feral Hog Bait will be disposed of by Genesis Laboratories, Inc. at the conclusion of the study.

9. Special Concerns

Four special concerns have been addressed to meet suitable risk to implement a feral hog toxicant using warfarin as an active.

1) Large amounts of anticoagulant bait in bait stations: There is concern that there will be a large amount of toxic bait in relatively small areas. This could pose a risk to non-target animals if they are able to access the bait stations.
Response: The HOGHOPPER™ bait stations have been thoroughly tested and found to be effective at eliminating access to non-target animals. The bait stations will be continuously monitored by motion activated camera to assure that non-target animals are unable to gain access to the bait. At the concentrations proposed in this study the bait requires multiple exposures to be lethal to non-target animals. Given the unlikely access of non-targets to the bait and the continued monitoring it is extremely unlikely that non-target animals would be at risk from the presence of large amounts of bait in the bait stations. Additionally, by having the bait in specific sites rather than broadcast it will limit the number of non-target animals that will be in close proximity of the test substance and therefore reduce potential for non-target animal exposure.

2) Spillage from the bait station during feral hog consumption: There is concern that some of the bait may be spilled by the feral hog or that small amounts might be transported by the feral hogs to distant locations and not consumed. This could make the bait available to non-target animals as primary consumers.
Response: While some spillage is possible it should not pose a threat to non-target animals for the following reasons: Any spillage will likely be limited to small areas localized around the bait station. The bait is specifically designed for optimal palatability for feral hogs and as such it is likely that many non-target animals will not find it palatable. The active concentration is low and would require multiple feedings to cause poisoning. The bait stations will be regularly monitored and if spillage of bait is observed it will be removed to prevent non-target access. Access to enough spilled feed for multiple feeding is unlikely from spilled feed. Additionally, the active in use has a vitamin K antidote for inadvertent exposure to companion animals.

The greatest overall risk assessment for birds and mammals as determined by (Erickson & Urban, 2004) for 250 ppm warfarin showed a greatest primary risk to birds to be 0.04 and for mammals 0.83. When adjusted by $1/5^{th}$ for the proposed bait at that is $1/5^{th}$ 250 ppm the concentration, the greatest primary risk for birds drops to 0.008 and for mammals 0.17. This level of risk is quite low considering that there are additional procedures in the bait presentation to further limit non-target exposure.

Genesis Laboratories, Inc. has conducted studies to assess risks to non-target animals that may directly consume warfarin baits. A 14 day choice test study with Bobwhite quail (*Colinus virginianus*) exposed to a bait with the same active as proposed in this EUP showed results that indicated the non-target exposure risk to be quite low(Soniat, 2010). The bait in the study was ground up to have a similar consistency to the challenge diet, which is a good representative of spilled or partially eaten baits by feral hogs. The choice test showed a low acceptance of 11%. This is to be expected when a bait formulation is designed for a different target animal and would suggest that non-target animals would choose other diets when available, which should be the case in the field setting for this study. In addition, the consumption of bait containing 250 ppm warfarin over 14 days did not lead to any observable signs of poisoning. A similar study was also done with Mallard duck (Anas platyrhynchos) exposed to a 250 ppm warfarin bait in a 14 day choice test and 7 day no choice test (Poche, 2008 MRID 48528603). This study showed an avoidance of the bait in the choice test and no signs of poisoning in the choice or no choice tests. In the table below please see a summary of toxicity studies conducted by Genesis Laboratories, Inc. The summary also includes studies conducted on other actives that are more toxic than warfarin.

Summary of Related Primary Exposure Studies Conducted by Genesis Laboratories, Inc.

Active Ingredient	Bait Concentration	Choice/ No Choice	Test Animal	Mortality	Reference/ MRID
Warfarin	250 ppm	Choice	Bobwhite Quail	None	Genesis 10010
Warfarin	250 ppm	Both	Mallard	None	48528603
Diphacinone	25 ppm	Choice	Mallard	None	48373005
Diphacinone	25 ppm		Bobwhite Quail	None	48373002

3) Secondary Poisoning of Birds and Mammals from Poisoned Hogs: There is concern that the feral hogs that consume the bait be consumed by predators and scavengers that could acquire the toxin secondarily.

Response: Feral hogs are particularly sensitive to warfarin. When chronically exposed the LD50 is 0.05 mg/kg/day for 7 days. For this reason relatively low concentrations of active in the bait are effective. With the concentration of active

proposed it is expected that the residues in the tissues of baited feral hogs will be at low risk levels. (Saunders, Kay, & Parker, 1990) determined that secondary poisoning risks are low due to the fact that warfarin residues in feral hog tissues decline rapidly and that baited feral hogs typically die several days after the poison has been consumed. Considering that the mean half-life of warfarin in humans is only 42 hours (Penumarthy & Oehme, 1978), and that bait consumption will decrease rapidly when toxicological symptoms begin, it is reasonable to conclude that feral hogs that die due to bait consumption should pose minimal risk to scavengers and predators.

The greatest overall risk assessment for birds and mammals as determined by (Erickson & Urban, 2004) for 250 ppm warfarin showed a greatest secondary risk to birds to be 1.72 and for mammals 1.32. When adjusted by $1/5^{th}$ for the proposed bait at that is $1/5^{th}$ 250 ppm the concentration, the greatest secondary risk for birds drops to 0.34 and for mammals 0.26. This level of risk is quite low considering that the residues in the carcasses of feral hogs should decline rapidly.

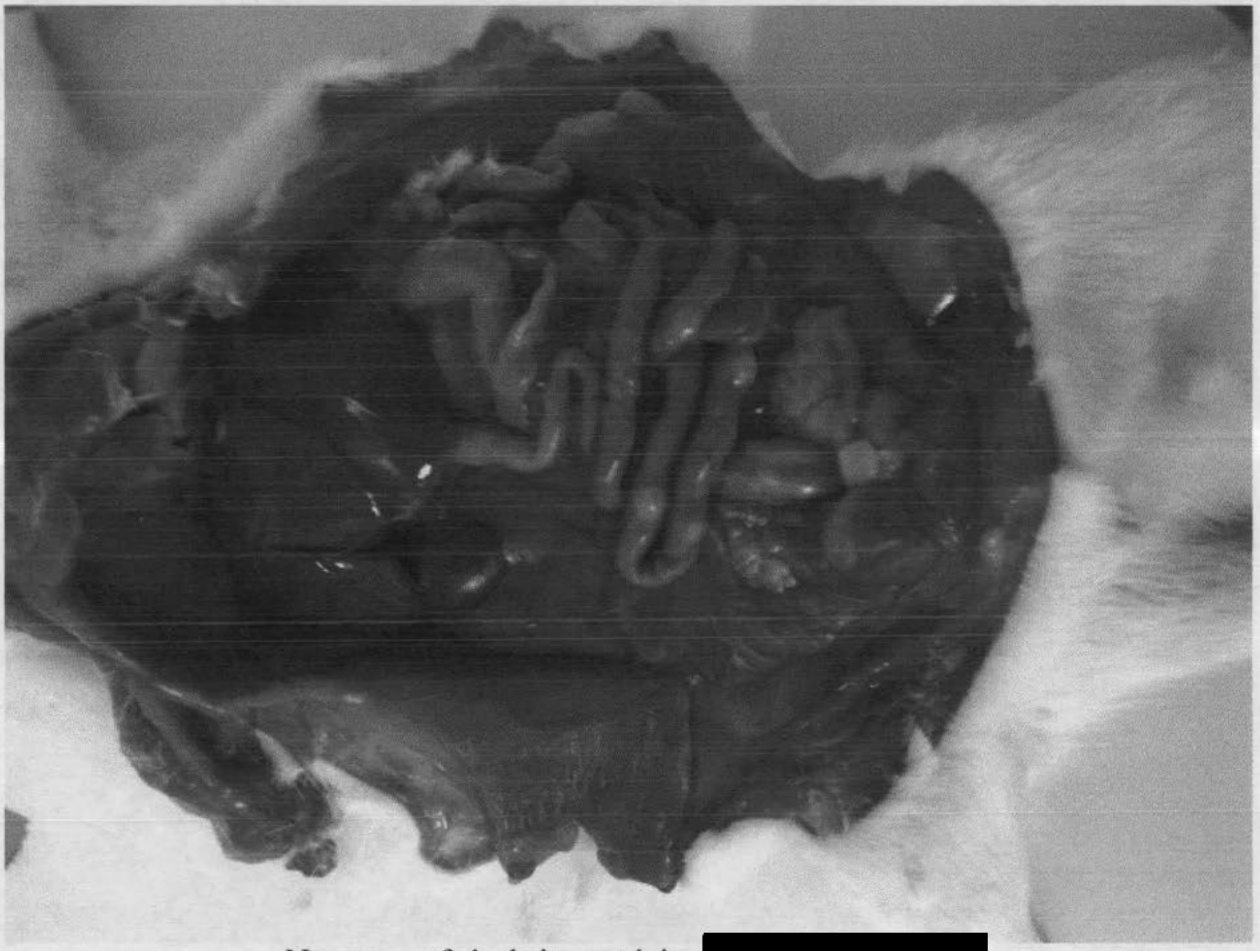
Genesis Laboratories, Inc. has conducted several studies to investigate to possible secondary toxicity to various animals that consume carcasses of warfarin poisoned animals. A study of Black-billed Magpies (*Pica pica*) that were fed warfarin poisoned Norway rat carcasses for 5 consecutive days showed zero mortality (Mach, Jeff J. and March, 1997 MRID 44995004). The Norway rats were fed a 500 ppm bait until mortality was observed which is 10 times higher than the concentration proposed in this EUP application. A similar study of domestic ferrets (*Mustela putorius furo*) that were fed warfarin poisoned Black-tailed prairie dogs (*Cynomys ludovicianus*) carcasses for 5 consecutive days showed zero mortality (Mach, 1998 MRID 44995003). A secondary toxicity study using the American Alligator (*Alligator mississsippiensis*) that were fed warfarin poisoned Norway rat carcasses for 5 consecutive days showed zero mortality(Poché, 2008 MRID 48373008). Warfarin blood residues were investigated and a maximum of 200 ppb was detected and a mean of 110 ppb at 1 day after exposure. The Norway rats in this study were fed a 250 ppm warfarin bait until mortality was observed. In the table below please see a summary of secondary toxicity studies conducted by Genesis Laboratories, Inc. The summary also includes studies conducted on other actives that are more toxic than warfarin.

Summary of Secondary Toxicity Studies Conducted by Genesis Laboratories, Inc.

Active Ingredient	Bait concentration given to primary animal	Secondary Animal	Mortality	Reference MRID
Warfarin	500 ppm	Black-billed Magpie	None	44995004
Warfarin	500 ppm	Domestic Ferret	None	44995003
Warfarin	250 ppm	American Alligator	None	48373008

Bromadiolone	50 ppm	Prairie Rattlesnake	None	

4) Consumption of Poisoned Animals by Humans: There is concern that may people hunt and eat feral hogs and could potentially eat a feral hog that has eaten the bait. Response: We have developed a strategy to use [redacted] in the baits. When eaten this dye will be sequestered in that fat of the animal turning the fat tissue a bright blue color. The color alone should be enough to discourage any consumption of the dyed animal products. However, advertisement can be included in hunting regulations to warn hunters not to eat tissues from animals that show the blue color. Please see the attached picture to see that dramatic effect of the [redacted] that should drastically discourage human consumption of any poisoned feral hog.



Norway rat fed a bait containing [redacted]

5) Risk of Warfarin Entering Ground Water: The baits will be exclusively used in bait stations that will keep the bait off the ground and out of any standing water. The solubility of warfarin is only 17mg/l limiting the risk of hazardous amounts of warfarin entering the ground water. Additionally, the bait will be in a wax

Inert ingredient information may be entitled to confidential treatment

block form which will further prevent the possibility of warfarin leaching out of the bait and into the ground water.

References:

Erickson, W., & Urban, D. (2004). *Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals : a Comparative Approach* (pp. 1–225).

Godfrey, M., & Lyman, C. (1980). Preliminary dosing trials of a new anticoagulant, brodifacoum, as a toxicant for the rabbit, Oryctolagus cuniculus (L.). *New Zealand journal of experimental ...*, (May 2013), 37–41. Retrieved from http://www.tandfonline.com/doi/full/10.1080/03015521.1980.10426224

Mach, J. J. (1998). *Secondary Hazard Study Using Warfarin-Killed Prairie Dogs (Cynomys ludovicianus) Fed to Domestic Ferrets (Musetla putorius furo)* (pp. 1–64).

Mach, Jeff J. and March, K. L. (1997). *Secondary Hazard Study Using Warfarin-Killed Laboratory Rats Fed to Black-billed Magpies (Pica pica)* (pp. 1–21).

Penumarthy, L., & Oehme, F. (1978). Treatment and protherombin responses during warfarin toxicosis in rats and mice. *Toxicology*, *10*, 377–401. Retrieved from http://www.sciencedirect.com/science/article/pii/0300483X78900859

Poché, Richard M., and Jeff J. Mach. "Wildlife primary and secondary toxicity studies with warfarin." *ACS Symposium Series*. Vol. 771. Washington, DC; American Chemical Society; 1999, 2000.

Poche, D. (2008). *Exposure of Nutria Bait to Mallard Ducks (Anas platyrhynchos)* (pp. 1–20).

Poché, R. M. (2008). *Secondary Toxicity Study with American Alligators (Alligator mississippiensis) fed Warfarin Killed Norway Rats (Rattus norvegicus)* (pp. 1–26).

Saunders, G., Kay, B., & Parker, B. (1990). Evaluation of a warfarin poisoning programme for feral pigs (Sus scrofa). *Wildlife Research*, (1987), 525–533. Retrieved from http://www.publish.csiro.au/?paper=WR9900525

Soniat, M. (2010). Exposure of Kaput Combo Bait Mini Blocks to Northern Bobwhite Quail (Colinus virginianus) EPA Registration No. 72500-14, (72500), 1–40.

EXPERIMENTAL USE PERMIT APPLICATION

BY:

Scimetrics Ltd. Corp.
Wellington, CO 80549

TITLE:

Field Efficacy of Kaput® Feral Hog Bait for Population Control of Feral Hog (Sus scrofa) in Texas

DATE OF APPLICATION:

June 7, 2013

MAIN CONTACT:

Sue Valentine
Scimetrics Ltd. Corp.
P.O. Box 1045
Wellington, CO 80549
Ph. 970-482-1330
sue@scimetricsltd.com

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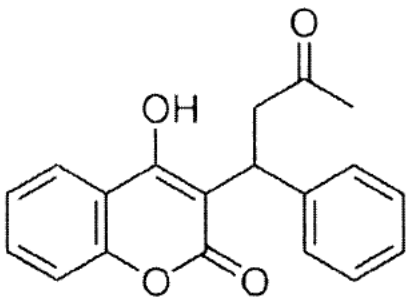
Section A: Chemical and Physical Properties of Test Chemical and Statement of Formulation of Active and Inert Ingredients.

TEST CHEMICAL: Warfarin $C_{19}H_{16}O_4$ (M.W. 308.4g)



NOMENCLATURE: Common name warfarin (BSI, E-ISO, BAN); warfarine ((m) F-ISO); coumafène (France); zoocoumarin (USSR); coumarins (JMAF, also applied to coumatetralyl *(q.v.)*; no name (The Netherlands).
IUPAC name (RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin;
3- *(α* -acetonyl benzyl) -4-hydroxycoumarin
Chemical Abstracts name 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-1-benzopyran-2-one
Other names coumaphene
CAS RN *[81-81-2]* unstated stereochemistry; *[5543-58-8]* (R)-(+)-
isomer; *[5543-57-7]* (S)-(-)- isomer EC no. 201-377-6 *(RS)·* isomers; 226-908-9 *(R)·* isomer; 226-907-3 (S)- isomer

PHYSICAL CHEMISTRY: Mol. wt. 308.3 M.f. $C_{19}H_{16}0_4$
Form The racemate forms colourless crystals. **M.p.**161-162°C **V.p.**1.5 x 10^{-3} mPa **Solubility** In water 17 mg/l (20°C). Very slightly soluble in benzene, diethyl ether and cyclohexane. Moderately soluble in methanol, ethanol and isopropanol. In acetone 65, chloroform 56, dioxane 100 (all in g/1, 20°C). Dissolves in aqueous alkalis with the formation of water-soluble salts. Sodium salt: in water up to 400 g/1; insoluble in organic solvents. **Stability** Very stable, even to strong acids. **pKa** It is acidic

APPLICATIONS: Biochemistry General internal bleeding is induced by reduction of the prothrombin content of the blood. **Mode of action** Anticoagulant rodenticide. Repeated ingestion is necessary to produce toxic symptoms. The (5)-(-)- isomer has 7-fold greater rodenticidal activity than the (R)-(+)- isomer (B. D. West et al., J. *Am. Chem. Soc.*, 1961, 83, 2676). **Uses** Control of rats and mice; also control of grey squirrels for tree protection, by presentation of bait in special hoppers. There is no tendency to bait-shyness. **Compatibility** Compatible with other rodenticides.

Confidential Statement of Formula may be entitled to confidential treatment

Section B: Proposed Experimental Label

FOR EXPERIMENTAL USE ONLY
Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program.

Kaput® Feral Hog Bait

Active Ingredient:	
Warfarin (CAS Number 81-81-2)	0.005%
Other Ingredients	99.995%
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back [side] panel for First Aid and additional Precautionary Statements.

EUP No. _____ EPA Est. 72500-CO-1

Net Wt. _____ lbs.
{25 lbs. - 100 lbs.}
[11.34 kg – 45.36 kg]

{Back/Side/Below}

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
This label must be in the user's possession at the time of product application.

READ THIS LABEL:
Read this entire label and follow all use directions and use precautions.
IMPORTANT: Do not expose children, pets, domesticated animals or other non-target wildlife to this product. To help prevent accidents:

1. Store product not in use in locations out of reach of children, pets, domesticated animals and wildlife.
2. Apply this product only as specified on this label.
3. Dispose of product container as well as unused, spoiled, or recoverable unconsumed bait, as specified on this label.

USE RESTRICTIONS: This product may be used to control only feral hogs (*Sus scrofas*) on rangeland, forests, non-crop areas, and crop lands.

- Do not apply this bait on the ground.
- Use a HOGHOPPER™ feeder or similar feeder with heavy lid that prevents non-target animals from accessing the bait.
- Apply bait in fenced areas and avoid application in open range areas.
- Wear protective gloves when handling bait or animal carcasses.
- Store this product out of reach and away from humans, domesticated animals, pets and wildlife.

- Do not allow young children, pets, domesticated animals or persons not associated with the application to be in areas where the bait is being applied.

SITE ASSESSMENT: Before applying this product, observe the area to identify where feral hog activity and trails are evident. Look for damaged crops, rutting of the soil and tracks to ensure activity in the area.

BAIT APPLICATION: Place 25-100 pounds of bait into each feeder. The animal access door must be closed limiting access only to feral hogs. Treatment should continue for 10-21 days and the feeder monitored and refilled as needed, approximately every 2-5 days depending on number of feral hogs visiting the feeder. **Leave no bait on soil surface or outside the feeder.** Collect and properly dispose of all bait that may have spilled outside the feeder. After treatment, collect and properly dispose of any bait that may have fallen out of the feeder.

SURVEILLANCE AND FOLLOW UP: Dead feral hogs may begin to appear in or near the treatment areas within 4-7 days after bait placement. Applicators must return to the treatment site within 4 days of application, and at 2-5 day intervals thereafter, to inspect each feeder and to collect and properly dispose of any bait or dead or dying feral hogs found on the surface. All carcasses found must be collected and disposed of properly. Bury carcasses on site in holes dug at least 18 inches deep. If burial is not practical (due to frozen ground, etc.) and other disposal methods are allowed by state and local authorities, collected carcasses may be disposed of by other methods to insure that carcasses are inaccessible to scavengers. Continue to collect and dispose of feral hogs and search for non-target animals for at least two weeks after the last filling of the bait feeder boxes. Deaths of any animals other than feral hogs, that appear to be the result of baiting, must be reported to state authorities.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container in a cool, dry place inaccessible to children and pets.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Handling:** Non-refillable container; do not reuse or refill this container. Offer for recycling, if available, or reconditioning, if appropriate; otherwise, dispose of empty container in a sanitary landfill.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Keep away from humans, domestic animals and pets. Any person who retrieves carcasses or unused bait following application of this product must wear protective gloves.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Poison Information Center at 1-800-858-7378 for emergency medical treatment information.

If swallowed, immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If in eyes, hold eye open and rise slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian at once.

NOTE TO PHYSICIAN OR VETERINARIAN

Contains Warfarin, an anticoagulant. If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. For humans or animals that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

ENVIRONMENTAL HAZARDS

This product may be toxic to fish, birds and other wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait. Do not apply this product directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash waters.

Manufactured by:
Scimetrics
LTD. CORP.
New Solutions to Old Problems
[Pest Management Solutions]
P.O. Box 1045
Wellington, CO 80549
(970) 482-1330
customerservice@kaputproducts.com
Made in USA

{ } Denotes language that does not appear on the market label
[ ] Denotes alternate language

Section C: Toxicity Data

Warfarin Toxicity Data

Species	Acute Oral LD50 (mg/kg)[1]	Chronic Oral LD50 (mg/kg/day)[1]
Mouse	374	0.6 for 3-9 days
Rat	3.0	0.4 for 4-15 days
Rat	50-100	1 for 5 days
Rabbit	800	30.0 for 6-15 days
Swine	3	0.05 for 7 days
Dog	20-50	5 for 5-15 days
Cat	6-40	3.0-5.0 for 10 days
Cat	5-50	1for 5 days
Ruminants	-	200 for 12 days
Chicken	1000	-

[1] Timm, R. M. 1994 Vertebrate Pesticides. Pages G26-G29 In (S.E. Hyngstrom, R. M. Timm, and G. E. Larson, eds.) Prevention and Control of Wildlife Damage. University of Nebraska Cooperative Extension.

Adjusted Toxicity Data for Warfarin Concentration Found in Bait

Species	Acute Oral LD50 (mg of Bait/kg)	Chronic Oral LD50 (mg of Bait/kg/day)
Mouse	7,480,000	12,000 for 3-9 days
Rat	60,000	8,000 for 4-15 days
Rat	1,000,000-2,000,000	20,000 for 5 days
Rabbit	16,000,000	600,000 for 6-15 days
Swine	60,000	1,000 for 7 days
Dog	400,000-1,000,000	100,000 for 5-15 days
Cat	120,000-800,000	60,000-100,000 for 10 days
Cat	100,000-1,000,000	20,000 for 5 days
Ruminants	-	4,000,000 for 12 days
Chicken	20,000,000	-

MAMMALIAN TOXICOLOGY: **Oral** Acute oral LD50 for rats 186, mice 374 mg/kg. Oral LD50 for rats 1, pigs 1, cats 3, dogs 3, cattle 200 (all mg/kg daily for 5 days). **ADI/RID** (EC) Not applicable [2006]; (EPA) cRfD 0.0003 mg/kg b.w. [1988]. **Other** Organ damage is observed, as well as inhibition of blood coagulation. Only slightly dangerous to humans and domestic animals when used as directed, but care must be taken with young pigs, which are especially susceptible. **Toxicity class** WHO (a.i.) lb; EPA (formulation) I. **EC classification** R611 T; R48/251 R52, R53 for (R)-, (5)-, or (RS)- isomers).

Section D: Residue Data

Not applicable – Studies will be completed on rangelands and the product will be applied in a HOGHOPPER™ or similar feral hog specific feeder.

Section E: Effectiveness Data

The effectiveness of this product will be determined by the data generated from this EUP research. However, previous studies conducted by Genesis Laboratories, Inc. have shown 100 % efficacy of a 0.005 % warfarin feral hog bait in pen trials. The acute LD50for warfarin in swine is 3 mg/kg for single dose or 0.05 mg/kg for 7 days. In light of this data we are confident that bait formulations used in this EUP research will be shown to be effective.

Section F: Tolerance Data

There are no EPA Maximum Residue Levels for residues of warfarin in food or feed. The product will be applied in a manner to prevent contact with vegetation or crops. All test animals that consume the test product will be sampled to determine residue levels. [redacted] will also be evaluated on test animals as a preventative against human consumption of exposed animals. The test animals will be disposed to prevent any consumption of test animals.

Inert ingredient information may be entitled to confidential treatment

Section G: Proposed Experimental Program

1. Participants and Collaborators

Field testing using Kaput® Feral Hog Bait containing 0.005% warfarin will be organized and completed by Genesis Laboratories, Inc. having its principle place of business at 10122 N.E. Frontage Rd., Wellington, CO 80549. All major participants in this study will be University graduates with backgrounds in biology wildlife biology or associated field. The key participants are:

Richard M. Poché	President and Technical Manager of Genesis Laboratories, Inc. with an M.S. in Wildlife Biology and over 40 years of experience in pest control product development. I have conducted research in over 50 countries including projects in wildlife management and management of invasive and pest species. I have led development of several pest and vector management products which includes acquiring patents and bringing products to market.
Robyn R. Raban	Senior Vector Ecologist at Genesis Laboratories, Inc. with M.S. in Medical Entomology and Ph.D. candidate in Vector Biology and Arbovirology. Has been the principal investigator for multiple vector control projects.
Christopher S. DePerno	Associate Professor, Fisheries, Wildlife, and Conservation Biology at North Carolina State University. Certified Wildlife Biologist with over 22 year of experience and over six years of experience conducting feral hog disease research.
Kevin J. Aldrich	Biologist/Assistant Lab Manager at Genesis Laboratories, Inc. with a M.S. in Biology and over 12 years of laboratory and research experience. I have conducted research in, wildlife management, animal disease diagnostics, swine epidemiology research, and ecotoxicology research. I have been the study director for multiple animal research projects and have extensive experience as an Institutional Animal Care and Use Committee (IACUC) chairperson.

2. State in Which Product will be used

This study will be conducted in the state of Texas with final field locations yet to be determined. The field sites will be determined based on sufficient numbers of feral hogs and perimeter fencing to eliminate human disturbance to field sites.

The treatment area will be approximately 1- 10 km^2 depending of feral hog densities. Study site will be chosen to ensure 50 to 100 feral hogs. The treatment area will not exceed 10 km^2. The total amount of bait applied will not exceed 10,000lbs.

3.

Target Species	Feral hog (Sus scrofa)
Location of Study	Texas: Hall, Motley, Jones, or Briscoe counties.
Sites of Application	Bait will be applied in feeders located at sites with active feral hog sign. The feeders will be spaced to limit duplicate hog visitation.
Desire Time of Application	Bait may be applied from spring to summer and not overlapping big game hunting seasons.
Use Pattern	Bait stations will be regularly monitored and will be kept filled for the duration of the 3 week experimental phase of the study.
Plot Size	Not to exceed 10 km^2 or 2,471 acres.
Dose Rate	Ad libitum. 25-100 lbs. of bait will be applied to each bait station.
Frequency of Application	Bait stations will be refilled as needed for the duration of the 3 week experimental phase. Approximately every 3-4 days.
Method of Application	Bait will be presented in feeders designed to restrict access animals other than feral hogs.
Season of Use	Late spring, summer, or early fall.
Amount of bait required	Kaput® Feral Hog Bait maximum amount required =12,600 lbs.
Amount of Active Required	0.63 lbs. warfarin.
Disposition of Unused Bait	Genesis Laboratories, Inc. will arrange to have unused bait incinerated.

4. Information on Prior Testing.

Previous work conducted at Genesis Laboratories, Inc. has provided preliminary data needed for this field study. In pen trials several bait concentrations were evaluated for efficacy as a feral hog bait. Baits with warfarin concentrations of 0.025% were found to have 100% efficacy when fed for 2 days. Baits with warfarin concentrations of 0.0125% were found to have 100% efficacy when fed for 5 days. Baits with warfarin concentrations of 0.005% were found to have 100% efficacy when fed for 5 days. Based on these results it was determined that bait with 0.005% warfarin would be effective and reduce any risk to non-target animals.

A 0.005 % warfarin bait such as Kaput® Feral Hog Bait provides several advantages. With anticoagulant baits such as this symptoms of poisoning will not develop until after a lethal dose is consumed preventing development of bait shyness(Godfrey & Lyman, 1980). Therefore, baits can be used that require multiple feedings to provide a lethal dose. Because the warfarin bait lends itself to multiple feedings it allows for the dose to be reduced drastically which will reduce risk to non-target animals. With multiple doses

required, non-target poisoning is much less likely because the non-target animals will need to consume multiple doses in succession to receive a lethal dose. In the same manner multiple doses reduce the risks of secondary.

5. Objectives of the proposed EUP program

The objectives of the proposed study are to determine the following:

A. To determine the efficacy of Kaput® Feral Hog Bait for control of feral hogs, containing 0.005% warfarin, when presented in HOGHOPPER™ feral hog feeders in a field setting.

B. To generate product performance data in support of FIFRA registration for Kaput® Feral Hog Bait for control of feral hogs.

C. To generate safety data during field use of product including; preventing non-target animal exposure by using hog specific bait station, preventing potential human exposure by evaluating [redacted] presence in baited animals, and determining secondary exposure risk by evaluating residue levels in tissues of baited animals.

6. Justification of Quantity of Material Requested

The material requested was calculated by estimating the consumption for an average size feral hog at approximately 100 lbs. A hog this size would typically need about 5-6 lbs. of grain per day. Therefor for a maximum of 100 hogs that consume 6 lbs. bait per day for the maximum of 21 days of treatment we will use a maximum of 12,600 lbs. The actual amount used will not exceed 12,600 lbs. and will be monitored and documented. Any excess test material will be incinerated.

7. Duration of the EUP program

The study will include a pre-exposure census of approximately 3 weeks. During this time a passive tracking index will be calculated following the method described by (Engeman, Constantin, Nelson, Woolard, & Bourassa, 2001). Additional census methods may be employed as needed depending or terrain and population densities. The exposure period will be conducted directly following the pre-exposure census and will last up to 3 weeks. Following the exposure period there will be a 3 week post-exposure census. The total duration of the experimental phase of the study will be approximately 9 weeks with up to 3 weeks of bait application. The duration may be longer if data justify a need for additional study.

Inert ingredient information may be entitled to confidential treatment

Study Phase	Approximate Duration
Pre-exposure census	3 Weeks
Exposure period	3 Weeks
Post-exposure census	3 Weeks

8. Disposition of any Unused Material

Any remaining Kaput® Feral Hog Bait will be disposed of by Genesis Laboratories, Inc. at the conclusion of the study.

9. Special Concerns

Four special concerns have been addressed to meet suitable risk to implement a feral hog toxicant using warfarin as an active.

1) Large amounts of anticoagulant bait in bait stations: There is concern that there will be a large amount of toxic bait in relatively small areas. This could pose a risk to non-target animals if they are able to access the bait stations.
Response: The HOGHOPPER™ bait stations have been thoroughly tested and found to be effective at eliminating access to non-target animals. The bait stations will be continuously monitored by motion activated camera to assure that non-target animals are unable to gain access to the bait. At the concentrations proposed in this study the bait requires multiple exposures to be lethal to non-target animals. Given the unlikely access of non-targets to the bait and the continued monitoring it is extremely unlikely that non-target animals would be at risk from the presence of large amounts of bait in the bait stations. Additionally, by having the bait in specific sites rather than broadcast it will limit the number of non-target animals that will be in close proximity of the test substance and therefore reduce potential for non-target animal exposure.

2) Spillage from the bait station during feral hog consumption: There is concern that some of the bait may be spilled by the feral hog or that small amounts might be transported by the feral hogs to distant locations and not consumed. This could make the bait available to non-target animals as primary consumers.
Response: While some spillage is possible it should not pose a threat to non-target animals for the following reasons: Any spillage will likely be limited to small areas localized around the bait station. The bait is specifically designed for optimal palatability for feral hogs and as such it is likely that many non-target animals will not find it palatable. The active concentration is low and would require multiple feedings to cause poisoning. The bait stations will be regularly monitored and if spillage of bait is observed it will be removed to prevent non-target access. Access to enough spilled feed for multiple feeding is unlikely from spilled feed. Additionally, the active in use has a vitamin K antidote for inadvertent exposure to companion animals.

The greatest overall risk assessment for birds and mammals as determined by (Erickson & Urban, 2004) for 250 ppm warfarin showed a greatest primary risk to birds to be 0.04 and for mammals 0.83. When adjusted by $1/5^{th}$ for the proposed bait at that is $1/5^{th}$ 250 ppm the concentration, the greatest primary risk for birds drops to 0.008 and for mammals 0.17. This level of risk is quite low considering that there are additional procedures in the bait presentation to further limit non-target exposure.

Genesis Laboratories, Inc. has conducted studies to assess risks to non-target animals that may directly consume warfarin baits. A 14 day choice test study with Bobwhite quail (*Colinus virginianus*) exposed to a bait with the same active as proposed in this EUP showed results that indicated the non-target exposure risk to be quite low(Soniat, 2010). The bait in the study was ground up to have a similar consistency to the challenge diet, which is a good representative of spilled or partially eaten baits by feral hogs. The choice test showed a low acceptance of 11%. This is to be expected when a bait formulation is designed for a different target animal and would suggest that non-target animals would choose other diets when available, which should be the case in the field setting for this study. In addition, the consumption of bait containing 250 ppm warfarin over 14 days did not lead to any observable signs of poisoning. A similar study was also done with Mallard duck (Anas platyrhynchos) exposed to a 250 ppm warfarin bait in a 14 day choice test and 7 day no choice test (Poche, 2008 MRID 48528603). This study showed an avoidance of the bait in the choice test and no signs of poisoning in the choice or no choice tests. In the table below please see a summary of toxicity studies conducted by Genesis Laboratories, Inc. The summary also includes studies conducted on other actives that are more toxic than warfarin.

Summary of Related Primary Exposure Studies Conducted by Genesis Laboratories, Inc.

Active Ingredient	Bait Concentration	Choice/ No Choice	Test Animal	Mortality	Reference/ MRID
Warfarin	250 ppm	Choice	Bobwhite Quail	None	Genesis 10010
Warfarin	250 ppm	Both	Mallard	None	48528603
Diphacinone	25 ppm	Choice	Mallard	None	48373005
Diphacinone	25 ppm		Bobwhite Quail	None	48373002

3) Secondary Poisoning of Birds and Mammals from Poisoned Hogs: There is concern that the feral hogs that consume the bait be consumed by predators and scavengers that could acquire the toxin secondarily.

Response: Feral hogs are particularly sensitive to warfarin. When chronically exposed the LD50 is 0.05 mg/kg/day for 7 days. For this reason relatively low concentrations of active in the bait are effective. With the concentration of active

proposed it is expected that the residues in the tissues of baited feral hogs will be at low risk levels. (Saunders, Kay, & Parker, 1990) determined that secondary poisoning risks are low due to the fact that warfarin residues in feral hog tissues decline rapidly and that baited feral hogs typically die several days after the poison has been consumed. Considering that the mean half-life of warfarin in humans is only 42 hours (Penumarthy & Oehme, 1978), and that bait consumption will decrease rapidly when toxicological symptoms begin, it is reasonable to conclude that feral hogs that die due to bait consumption should pose minimal risk to scavengers and predators.

The greatest overall risk assessment for birds and mammals as determined by (Erickson & Urban, 2004) for 250 ppm warfarin showed a greatest secondary risk to birds to be 1.72 and for mammals 1.32. When adjusted by $1/5^{th}$ for the proposed bait at that is $1/5^{th}$ 250 ppm the concentration, the greatest secondary risk for birds drops to 0.34 and for mammals 0.26. This level of risk is quite low considering that the residues in the carcasses of feral hogs should decline rapidly.

Genesis Laboratories, Inc. has conducted several studies to investigate to possible secondary toxicity to various animals that consume carcasses of warfarin poisoned animals. A study of Black-billed Magpies (*Pica pica*) that were fed warfarin poisoned Norway rat carcasses for 5 consecutive days showed zero mortality (Mach, Jeff J. and March, 1997 MRID 44995004). The Norway rats were fed a 500 ppm bait until mortality was observed which is 10 times higher than the concentration proposed in this EUP application. A similar study of domestic ferrets (*Mustela putorius furo*) that were fed warfarin poisoned Black-tailed prairie dogs (*Cynomys ludovicianus*) carcasses for 5 consecutive days showed zero mortality (Mach, 1998 MRID 44995003). A secondary toxicity study using the American Alligator (*Alligator mississsippiensis*) that were fed warfarin poisoned Norway rat carcasses for 5 consecutive days showed zero mortality(Poché, 2008 MRID 48373008). Warfarin blood residues were investigated and a maximum of 200 ppb was detected and a mean of 110 ppb at 1 day after exposure. The Norway rats in this study were fed a 250 ppm warfarin bait until mortality was observed. In the table below please see a summary of secondary toxicity studies conducted by Genesis Laboratories, Inc. The summary also includes studies conducted on other actives that are more toxic than warfarin.

Summary of Secondary Toxicity Studies Conducted by Genesis Laboratories, Inc.

Active Ingredient	Bait concentration given to primary animal	Secondary Animal	Mortality	Reference MRID
Warfarin	500 ppm	Black-billed Magpie	None	44995004
Warfarin	500 ppm	Domestic Ferret	None	44995003
Warfarin	250 ppm	American Alligator	None	48373008

Bromadiolone	50 ppm	Prairie Rattlesnake	None	

4) Consumption of Poisoned Animals by Humans: There is concern that may people hunt and eat feral hogs and could potentially eat a feral hog that has eaten the bait. Response: We have developed a strategy to use [redacted] in the baits. When eaten this dye will be sequestered in that fat of the animal turning the fat tissue a bright blue color. The color alone should be enough to discourage any consumption of the dyed animal products. However, advertisement can be included in hunting regulations to warn hunters not to eat tissues from animals that show the blue color. Please see the attached picture to see that dramatic effect of the [redacted] that should drastically discourage human consumption of any poisoned feral hog.

Norway rat fed a bait containing [redacted]

5) Risk of Warfarin Entering Ground Water: The baits will be exclusively used in bait stations that will keep the bait off the ground and out of any standing water. The solubility of warfarin is only 17mg/l limiting the risk of hazardous amounts of warfarin entering the ground water. Additionally, the bait will be in a wax

Inert ingredient information may be entitled to confidential treatment

block form which will further prevent the possibility of warfarin leaching out of the bait and into the ground water.

References:

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